Adherence in an Optimized Program of Mindfulness Based Stress Reduction

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"How we see and hold the full range of our experiences in our minds and in our hearts makes an enormous difference in the quality of this journey we are on and what it means to us. It can influence where we go, what happens, what we learn, and how we feel along the way." *John Kabat-Zinn*

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Dedication

"A genuine friend encourages and challenges us to live out our best thoughts, honor our purest motives, and achieve our most significant dreams." *Dan Reiland*

My work is dedicated to my family and friends who have supported me through this journey. My decision to pursue higher education over the last six years has proved challenging at times, but has also been one of my most rewarding experiences. I knew receiving advanced degrees would give me the knowledge and resources necessary for me to reach my life long goal of teaching nursing. My husband, Jeff, has been extremely supportive and patient throughout this process. He has encouraged me in times of exhaustion, listened when I needed a friend, and remained constant in his understanding. Jeff, I am very thankful for all that you do and know that I would not be where I am today without you. I love you! Sharing the experience of getting our PhDs together made reaching this unique milestone even more special. Our lives became even more extraordinary when we welcomed our beautiful, curious, and playful daughter, Iris, into this world. Iris reminds us that every moment counts and that there is always time to play, no matter how much needs to get done or how busy our lives feel.

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Abstract

Objective: Mindfulness Based Stress Reduction (MBSR) programs have been successful in treating stress across various populations, however, little is known about how to best promote adherence to MBSR program teachings. The purpose of this dissertation study was to examine adherence to MBSR practice and the feasibility of a 12-session adherence enhancement intervention in the context of an MBSR and support group program. Measures included MBSR practice time, commitment and confidence for regular MBSR practice, and stress levels. Common themes of MBSR practice experiences that may have influenced adherence to the MBSR program teachings were also explored. **Design and Method:** An exploratory, single-group, longitudinal research design was used with a sample of 11 women. An adherence intervention package that included self-monitoring logs, telephonic coaching, and financial incentives were implemented over an 11-week period as subjects participated in an 8-session MBSR course supplemented with 4 support group sessions (i.e., 12 sessions total over 11 weeks). In addition, a series of qualitative, semi-structured interviews were administered at weekly intervals. **Findings:** On average, participants with complete baseline and follow-up measures had a statistically significant 9 point (49%) increase from baseline in their MBSR practice scores from a self-report survey. In addition, logged MBSR practice time increased by a non-significant 35 minutes per day between baseline and completion. Although commitment and confidence levels remained stable during the study, results from correlation analyses indicated that higher MBSR practice survey scores were significantly associated with lower stress levels. Qualitative interviews indicated that lack of routine, lack of time, and limited personal space were the most common barriers to regular MBSR practice. Participants

reported experiencing major emotional growth in regard to confronting and accepting their present stressors. **Conclusions:** The intervention package was feasible and acceptable to study participants, as indicated by the high degree of exposure to its components. There was also evidence indicting accelerating frequency of MBSR practice over time. However, improvements in commitment and confidence for regular MBSR practice, and stress levels were negligible. Future research should replicate the study intervention in a larger sample with more rigorous statistical controls.

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Chapter I: Introduction

This chapter introduces the rationale for addressing stress as a modifiable risk factor for chronic health conditions. An overview of a common type of stress reduction program, Mindfulness Based Stress Reduction (MBSR), is also described. MBSR programs have been successful in treating stress across a wide variety of populations. It is believed that benefits accrue from participation and adherence to recommended MBSR practices. However, there remain many unanswered questions about how to best promote adherence to MBSR program teachings. A rationale for addressing this issue in this dissertation research study is discussed in this section.

Chronic Stress and Health Consequences

Chronic stress has been associated with premature mortality (Kopp, Skrabski, Székely, Stauder, & Williams, 2007), as well as the incidence and severity of chronic health conditions (U.S. Department of Health and Human Services, 2000). The cardiovascular system is a primary target of the stress response (Matthews, Owens, Kuller, Sutton-Tyrrell, Lassila, & Wolfson, 1998), with many stress hormones being released that contribute to the development of cardiovascular events such as unstable angina and acute myocardial infarction (Kubzansky & Kawachi, 2000; Pashow, 1999; Robert-McComb, 2000; Rosengren et al., 2004). The physiological response to stress also increases glucose mobilization and insulin resistance (Rosmond, 2005; Surwit, Schneider, & Feinglos, 1992), contributing to metabolic syndrome and increased incidence of type 2 diabetes (Kawakami, Araki, Takatsuka, Shimizu, & Ishibashi, 1999). Some forms of cancer and depression have also been linked to hypersecretion of stress hormones, such as cortisol and interleukin-6 (Godbout & Glaser, 2006; Wolkowitz, 1994).

Fortunately, chronic stress is considered to be a modifiable risk factor for illness through adjustments made to an individual's environment and/or improvement of their behavioral coping mechanisms. Stress reduction interventions have been shown to improve glycemic control for patients with type 2 diabetes (Surwit & Schneider, 1993; Surwit et al., 2002) and have also been shown to reduce cardiac mortality (Dusseldorp, van Elderen, Maes, Meulman, & Kraaij, 1999). For women with breast cancer, reduction in stress hormones following a cognitive-behavioral stress management intervention led to improvements in immune function and increased ability to find positive attributes of their cancer diagnosis (Cruess, et al., 2000; McGregor, Antoni, Boyers, Alferi, Blomberg, & Carver, 2004). In addition, for patients with chronic immunosupression such as human immunodeficiency virus, cognitive-behavioral stress management interventions have been shown to reduce symptoms of depressed mood (Brown & Vanable, 2008).

Overview of MBSR

Stress management therapies may take various forms, for example yoga, meditation, music therapy, massage, or cognitive-behavioral counseling. Over the past decade, the use of these alternative and complementary therapies has become more widely accepted as part of standard medical care, especially among individuals who have been unresponsive to traditional therapies for chronic health conditions (Gross, Kreitzer, Russas, Treesak, Frazier, & Hertz, 2004). One specific form of stress management that has become increasingly popular in recent decades is MBSR. This program was developed by Jon Kabat-Zinn in the early 1980's (Kabat-Zinn, 1982) and further refined with colleagues at the University of Massachusetts as a participatory wellness program using meditation (Kabat-Zinn, 1990).

A typical MBSR program is taught in a group lasting eight sessions with a day long retreat around the seventh week (Kabat-Zinn, 1990; Salmon, Santorelli, Sephton, & Kabat-Zinn, 2009). Application of mindfulness skills including body scan, sitting/lying meditations, mindful walking/eating, and Hatha yoga, enable participants to focus more on the present. The general acceptance of one's mind-body experiences is promoted, which likely promotes physical relaxation. MBSR programs are becoming more prevalent. An estimated 240 hospitals and clinics worldwide currently offer MBSR programs (Salmon, Santorelli, Sephton, & Kabat-Zinn, 2009).

Problem Statement

MBSR appears to be an efficacious therapy for several health conditions where mental stress or general anxiety is associated with the sequale of decreased physical functioning and quality of life**.** However, like any behaviorally oriented therapy, achieving optimal results in a given MBSR program likely requires a high degree of adherence to the MBSR teachings. In other words, it is believed that participants need to attend the weekly sessions, practice meditation at home, and apply mindfulness skills in everyday life situations in order for the program to be maximally effective (VanWormer, & Lindquist, 2010). However, there is a major gap in the published evidence base pertaining to MBSR in that the degree to which participants actually adhere to the actions recommended in their MBSR program is largely unknown. Also, little is known about what techniques have been used above and beyond standard MBSR programs to help encourage and reinforce adherence to mindfulness practices.

Study Purpose

Enhancing adherence to overall MBSR practice time has yet to be studied directly. Given the most common barriers for participants who prematurely drop out of MBSR programs are lack of time, busy schedules, and lack of motivation (Gross et al., 2004; Anderson, Lau, Segal, & Bishop, 2007), it seems timely to explore adherence in the context of an MBSR program employing an "adherence intervention package." The package incorporates self-monitoring in addition to strategies that have worked well in other areas of behavior modification, such as telephonic coaching (Cook, Emiliozzi, & McCabe, 2007) and financial incentives (VanWormer & Pronk, 2009). In addition to the quantitative evaluation of adherence, a more detailed qualitative inquiry is also needed to understand inter-individual variability in MBSR adherence and how particular adherence enhancement efforts are received by participants and may influence specific MBSR practices.

The purpose of the *Stress Management, Incentives, Logging, and Enhancements* (SMILE) study, which was the focus of the author's dissertation research, was to examine the impact of a 12-session adherence enhancement intervention on MBSR practice time, potential mediators of MBSR practice, and stress levels over 11 weeks. In addition, common themes of MBSR practice experiences that may have influenced adherence to the MBSR program teachings were explored.

The SMILE study was expected to produce in-depth data in several domains. It was designed to provide a more detailed examination of subjects' participation in each aspect of an MBSR program. This information could then be used to inform the design of future programs that optimize the benefits of consistent adherence to MBSR teachings.

Furthermore, the SMILE study was designed to explore the possibility of identifying the point at which stress reduction benefits begin to meaningfully accrue relative to the degree of MBSR program exposure. In future studies, these learnings can be used to prescribe and reinforce more precise MBSR practice goals based on their expected benefit.

Chapter II: Review of the Literature

Eight systematic reviews examining the effectiveness of MBSR on health outcomes were explored in the sections below. MBSR has shown benefits across a wide range of populations and health ailments. These benefits are reviewed in this chapter. A special focus is placed on reviewing interventions that measured adherence to MBSR practice. Specific adherence techniques above and beyond standard MBSR programs were also outlined.

MBSR Program

A standard MBSR program is taught over the course of eight sessions (~8-10 weeks) in a group format (Kabat-Zinn, 1990; Salmon, Santorelli, Sephton, & Kabat-Zinn, 2009). MBSR is a secular program of teaching meditation/yoga that is derived from Buddhist teachings. It emphasizes an attitude of non-judging, non-striving, acceptance, letting go, trust, and being fully present in the moment. In the program, individuals receive direct instruction, modeling, and performance feedback on several formal techniques, including body scan, sitting/lying meditations, mindful walking/eating, and Hatha yoga. Kabat-Zinn (1990) has recommended a minimum of 45 minutes of daily mindfulness practice in standard MBSR programs. Also, a day long silent retreat is typically held around the seventh week of the program to further crystallize participant's mindfulness skills (Kabat-Zinn, 1990; Salmon, Santorelli, Sephton, & Kabat-Zinn, 2009). During the silent retreat, participants are instructed not to talk in order to create a very intense awareness of themselves, others, their thoughts, and their interaction with a near stimulus-free environment.

MBSR encourages participants to become much more aware of their present surroundings and mind-body experiences as they occur (Salmon, Santorelli, Sephton, & Kabat-Zinn, 2009). These teachings promote the mind frame of "living in the now" and not expending energy on worrying about things that have happened in the past or things that may happen in the future. This active acceptance of one's current state of mind then subsequently promotes physical relaxation. Participants are encouraged to apply what they have learned to their everyday lives in acceptance of and deliberately responding to, rather than reacting to, stressors and challenges they face at work, home, and during leisure time. The MBSR model aims to teach individuals to break the conditioned chain of psychological and physical reactions to events associated with stressors that theoretically maintain a lifestyle of chronic stress. Instead, individuals are guided to respond more adaptively to perceived stressors and mental, physical, and emotional states.

Systematic Review Findings

The eight systematic reviews in this area made several important observations. Grossman and colleagues (2004) found that MBSR was a strong intervention for improving physical and mental wellbeing across the general population, as well as for reducing pain (average effect size = 0.5). Teixeira (2008) arrived at similar conclusions in regard to benefits for chronic pain suffers. Both Matchim et al. (2007) and Smith, et al. (2005) found statistically significant psychological improvements in depressed mood, quality of life, and generalized anxiety for individuals with cancer following completion of an MBSR program. Importantly in this same patient population, a general dose-response effect was reported related to increased practice time of MBSR (Smith,

Richardson, Hoffman, & Pilkington, 2005). Praissman (2008) concluded that MBSR intervention programs were effective stress reduction tools for a wide range of individuals and for healthcare providers in particular. Three of the eight published systematic reviews, however, concluded that there was inconclusive evidence on the efficacy of MBSR across several outcomes. Sleep (Winbush, Gross, & Kreitzer, 2007) and clinical depression (Toneatto & Nguyen, 2007) appear to be particularly less responsive to the practice of MBSR teachings. Bishop (2002) raised major concerns in regard to the lack of controlled research designs across the published MBSR literature and has asserted that more rigorous studies with stronger evidence are required before the healthcare community can embrace MBSR as a helpful complement to standard medical therapies for well defined purposes.

MBSR Participation and Adherence

At least 16 studies have been published in the scientific literature that examined MBSR programs with at least some level low intensity adherence interventions or adherence monitoring embedded into the standard training program materials and procedures (see Appendix A). These adherence intervention components most commonly included some form of self-monitoring. Adherence in these studies was commonly reported as the MBSR program completion rate, which is typically defined for an individual participant as having completed ≥5 of the 8 available MBSR sessions (not including the day-long retreat) (Salmon, Santorelli, Sephton, & Kabat-Zinn, 2009). Occasionally, adherence oriented results were also reported on overall MBSR practice time during the active MBSR intervention phase. These studies are reviewed below.

Carlson and Garland (2005) recruited 63 adults with cancer in Alberta, Canada. The mean age was 54 years, 78% were female, and 71% were married. A single group pretest-posttest design was used, with an adherence component that included meditation self-monitoring logs. The self-monitoring logs involved daily tracking of minutes spent in yoga and meditation. Results indicated that 100% of the participants completed 5 or more MBSR sessions. No results were reported on total logged MBSR practice time.

In a similar study, 59 adults with breast or prostrate cancer were recruited through clinic posters/pamphlets in Alberta Canada (Carlson, Speca, Faris, & Patel, 2007). The mean age was 55 years, 83% were women, and 71% were married. A single group pretest-posttest design was used with an adherence component that included meditation self-monitoring logs. The self-monitoring logs involved daily tracking of minutes spent in yoga and meditation. Results indicated that 52 (88%) of the 59 participants completed 5 or more MBSR sessions and that the average total home-based meditation/yoga practice time reported was 37 minutes per day (n=31).

Carmody, Reed, Kristeller, and Merriam (2008) conducted a study with 62 adults referred (for stress management) by their healthcare provider to an MBSR program in Massachusetts. The mean age was 48 years and 75% were female. A retrospective cohort design was used with an adherence component that included mindfulness self-monitoring logs. The self-monitoring logs involved daily tracking of minutes spent in formal (meditation) and informal (being mindful) home practice. Results indicated that 52 (84%) participants completed the program, however, completion of the MBSR program was not specifically defined. In addition, the average total home-based formal and informal practice time was 38 minutes per day (n=44).

Davidson and colleagues (2003) recruited 48 employed adults in a biotechnology corporation in Wisconsin. The mean age was 36 years and 71% were female. A randomized-controlled trial design was used with an adherence component that employed meditation self-monitoring logs. The self-monitoring logs involved daily tracking of minutes spent in formal meditation. Results indicated that 41 (85%) participants completed the program and that the average total home-based formal (meditation) practice time was 41 minutes per day (range 0-210; n=41). The total number of MBSR sessions completed was not included.

Another study in Wisconsin recruited 18 adult smokers (Davis, Fleming, Bonus, & Baker, 2005). The mean age of participants was 45 years and 56% were female. A single group pretest-posttest design was used and an adherence component that included meditation self-monitoring logs. The self-monitoring logs involved daily tracking of minutes spent in formal meditation. Results indicated that 13 (72%) participants completed 5 or more MBSR sessions and that the average total home-based formal (meditation) practice time was 33 minutes per day.

Marcus, et al. (2003) recruited 21 adult residents of a substance abuse center in Texas to participate in an MBSR program. The mean age of the sample was 33 years and 14% were female. A single group pretest-posttest design was used with a meditation self-monitoring log to measure MBSR practice. This log included daily tracking of minutes spent in meditation. Eighteen (86%) of the 21 participants completed the program, but the definition of “complete” was not explicitly reported. No results were reported on total logged MBSR practice time.

Beddoe and Murphy (2004) recruited 23 female nursing students through a Baccalaureate level education program in California into a study of the effects of MBSR on stress. The mean age was 25 years and a single group pretest-posttest design was used. An adherence component that included journal keeping was utilized. This involved non-directed encouragement to have participants write about feelings, adjustments, benefits, and progress regarding MBSR training. Results indicated that 18 (78%) of the 23 participants completed all eight MBSR sessions (not including the day-long silent retreat), but the journaling outcomes were not reported.

Kreitzer and colleagues (2005) recruited 20 adult organ transplant recipients in Minnesota for an MBSR study. The mean age of the sample was 49 years, 70% were female, and 30% were married. A single group pretest-posttest design was used with a meditation self-monitoring log as part of the MBSR program. This included daily tracking of minutes spent in meditation. In addition, weekly and monthly telephone follow-ups were also involved to encourage home meditation practice. Nineteen (95%) of the 20 participants completed 5 or more MBSR sessions (8 attended all 8 sessions). The average total home-based formal (meditation) practice time was approximately 25 minutes per day.

Koszycki, et al. (2007) recruited 58 adults with various social anxiety disorders in Ottawa, Ontario. The mean age of the sample was 38 years, 53% were female, and 30% were married. A randomized-controlled trial design was used with a meditation self-monitoring log. The self-monitoring log involved daily tracking of minutes spent in meditation. Twenty two (85%) of the 26 participants in the MBSR intervention group completed 5 or more MBSR sessions. Self-monitoring outcomes were not reported.

Pradhan, et al. (2007) recruited 63 adults with rheumatoid arthritis in Maryland. The mean age of the sample was approximately 54 years, 87% were female, and 63% were married. A randomized-controlled trial design was used with meditation self-monitoring logs to track daily MBSR practice. Twenty eight (90%) of the 31 participants in the MBSR program completed it (the median number of sessions attended was 8 of 8; interquartile range was 6-8). The average ±SD total home-based MBSR practice time was 47 ±21 minutes per day.

Sephton and colleagues (2007) recruited 91 female adults with fibromyalgia in Kentucky. The mean age was approximately 48 years and 60% were married. A randomized-controlled trial design was used with reminder telephone calls (to attend sessions) conducted after missed MBSR sessions. Forty two (82%) of the 51 MBSR program participants completed 4 or more MBSR sessions. Mean ±SD session attendance was 5.5 ±2.1 of the eight available sessions. It is unclear if the reminder phone calls influenced session attendance because this correlation was not performed in this study.

Shapiro, et al. (2007) recruited 64 adult students through graduate psychology courses in California. The mean age was 29 years and 90% were female. A non randomized-controlled quasi-experimental design was used with a meditation self-monitoring log to encourage daily tracking of MBSR practices. Twenty two (100%) of the 22 participants in the MBSR program completed it, however, no precise measures of MBSR program completion were reported. No results were reported on total logged MBSR practice time.

Morone and colleagues (2008) recruited 37 adults with chronic lower back pain in Pennsylvania. The mean age of the sample was 75 years, 57% were female, and 62%

were married. A randomized-controlled trial design was used with a meditation self-monitoring log to track daily minutes spent meditating. Thirteen (68%) of the 19 intervention group participants completed the program (average number of sessions attended was 6.7) and the average total (meditation) practice time was approximately 32 minutes per day (range 0-52).

Shapiro and colleagues (2008) recruited 47 adult students in California. The mean age was 29 years and 90% were female. A randomized-controlled trial design was used with meditation self-monitoring logs to encourage daily tracking of MBSR practice time. Fifteen (88%) of the 17 MBSR program participants completed the MBSR program. Despite the fact that 15 participants were reported to have completed the program, no precise measures of MBSR participation (classes attended) or practice time were given.

Kieviet-Stijnen and colleagues (2008) recruited 93 adult cancer patients from clinical practice in the Netherlands. The mean age was 48 years and 72% were female. A single group pretest-posttest design was used and an adherence component that included cognitive logs and personal training goals. The cognitive logs required that participants record frequent thoughts, stressful communications, and physical sensations. The personal training goals were non-specific. Results indicated that 77 (83%) participants completed the program. No precise measure of the number of MBSR sessions completed or the total logged MBSR practice time were reported.

Vieten, et al. (2008) recruited 34 pregnant female adults with self-reported mood disturbances in California. The mean age of the sample was 34 years and 100% were married. A randomized-controlled trial design was used with meditation self-monitoring logs to track daily tracking MBSR practices. Thirteen (87%) of the 15 participants in the

intervention group completed (not defined) the MBSR program, with a mean ±SD number of sessions attended being 7.2 ±1.1. and the mean ±SD amount of total time spent in MBSR activities was 11 ±4 minutes per day.

Summary of MBSR Adherence

The level of participation in MBSR programs with at least some form of adherence intervention beyond the standard MBSR training protocol, as characterized by program completion rates (i.e., attending ≥5 of the 8 available sessions), was found to be relatively high at a median of 86% across these 16 reviewed studies. This is also very consistent with the reported 15% average attrition rate for MBSR programs reported by the program's original research team (Salmon, Santorelli, Sephton, & Kabat-Zinn, 2009). Characterizing the precise pattern of decay was not possible, however, since attrition was not the focus within any of these studies and session completion was often ill-defined. As such, the participant characteristics and reasons why they dropped-out were not provided, indicating a major gap in the events reviewed. Given that the most common definition of completion reported was attending ≥5 sessions, it seems reasonable to conclude that most people who enroll in an MBSR program receive a fairly high degree of exposure to instructor-led sessions and, if they do drop-out, the assumption is that attrition tends to occur early on (VanWormer, & Lindquist, 2010), but it is unclear who or why. Therefore, it is unclear what standardized program completion criteria should be followed. In other words, the minimally beneficial number of MBSR sessions is currently unknown.

What may be more influential than MBSR session attendance is the total amount of time engaged in MBSR practice. In terms of home practice, a minimum of 45 minutes of daily mindfulness practice is recommended (Kabat-Zinn, 1990). However, it is not

clear if this is an empirically supported recommendation. The median amount of home based mindfulness practice reported in the reviewed studies was approximately 30 (11-50) minutes per day. Since very few studies report home practice in the first place, this makes this estimate potentially unreliable. Journals or tracking logs that were designed to encourage self-monitoring of home-based mindfulness practice, were the most heavily utilized adherence intervention, but it does not seem that self-monitoring alone is associated with appreciably higher completion rates than what can be expected with a standard MBSR program (without a daily tracking log). Also, the data generated from the tracking logs were not always reported. In other words, the use of journals or logs was acknowledged, but specific information (i.e., minutes of practice) was not provided. Studies that utilized any other additional adherence strategies, including basic telephone reminders, were very rare.

Overall, MBSR programs are generally well accepted and participants attend most of the classroom sessions offered. However, there remain significant gaps in reporting the details of various aspects of MBSR adherence. In particular, total MBSR practice time, detailed session attendance records (including day long retreat), log book completion, and adherence-stress associations often go unreported in published MBSR studies. Also, examples of comprehensive adherence enhancement to MBSR practice are non-existent and untested in the literature. This is unfortunate because, in addition to self-monitoring logs, combining other behavior modification techniques, such as telephone follow-ups using cognitive-behavioral counseling (Cook, Emiliozzi, & McCabe, 2007) and financial incentives contingent on program completion (VanWormer & Pronk, 2009), have been

shown to be effective strategies in other areas where adherence to a behavioral intervention is critical.

The SMILE study integrated such a comprehensive adherence enhancement package that included detailed MBSR self-monitoring logs with performance regularly reviewed and feedback given with routine telephonic coaching calls from a health professional. The weekly telephone calls were designed to last approximately 20 minutes and followed a general structure. Each call focused on a progress review on MBSR practice, supportive feedback for meeting personal goals, and problem-solving advice to address barriers to MBSR practice. In addition, completion of the daily MBSR self-monitoring logs was reinforced through weekly gift card raffles.

Conceptual Framework: Social Cognitive Theory

The conceptual framework for MBSR adherence (that informs the adherence enhancements as part of the SMILE study) was primarily based on Social Cognitive Theory (SCT). SCT was developed by Albert Bandura and essentially explains why and how people engage in behavioral patterns (Bandura, 1986). SCT hinges on the concept of reciprocal determinism, or the interaction between the behavior of interest, the individual, and the individual's environment. Specifically, the environment refers to the external physical and social factors that influence the behavior of interest. Social factors include things like conversations with family members, friends and colleagues. Physical factors include things like room characteristics, temperature, or access to certain facilities. The individual or personal components of reciprocal determinism include internal, cognitive representations of the environment, outcome expectations, and confidence for performing

the behavior of interest (Glanz, Rimer, & Lewis, 2002). In the SCT, these three factors are constantly influencing each other.

Central to the design of SCT-based interventions is improving behavioral capability. Behavioral capability refers to the individual's behavioral skills and knowledge, as well as cognitive and environmental factors that impact the potential of the individual to engage in the behavior of interest (Bandura, 1997). In the SMILE study, the behavior of interest was regular MBSR practice time. Specifically, it is recommended that participants practice MBSR techniques at least 45 minutes, six days a week (4.5 hours per week) during a standard MBSR program. During 11-weeks of the SMILE study, participants were instructed in various MBSR techniques under supervised situations during MBSR classroom sessions where they received further customized advice and feedback. The adherence enhancements were essentially designed to manipulate cognitive and environmental factors that, according to SCT, encouraged regular MBSR practice outside of classroom sessions (see Figure 1).

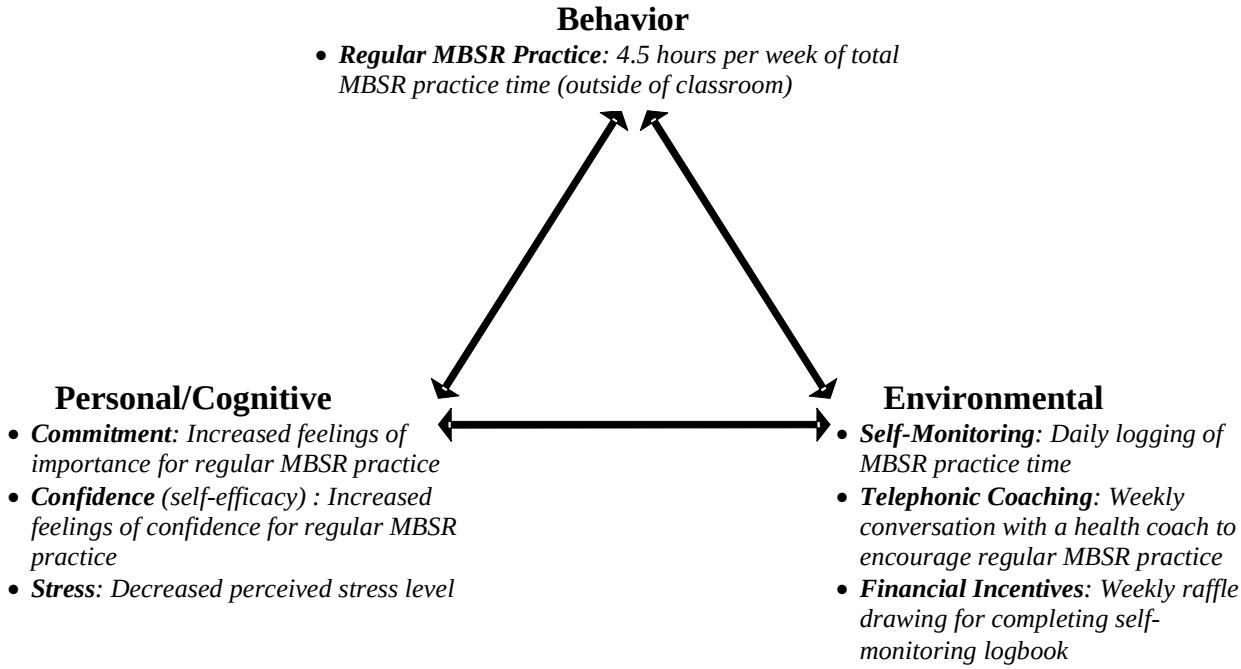
The specific cognitive and environmental factors from SCT that were targeted in the SMILE adherence enhancement package were:

1) *Self-control (or self-regulation)*: Participants were advised to self-monitor their MBSR practice daily using a logbook that was turned in at the end of each week. This provided participants frequent feedback on the amount of MBSR practice they engaged in so that comparisons could be made to their previous personal norms, as well the criterion amount recommended to them in their written MBSR materials and classroom instruction.

2) *Reinforcement*: Supportive feedback was given to participants as part of the telephonic coaching component of the intervention. During these weekly calls, participants' MBSR practice time was reviewed and the SMILE study principal investigator provided verbal praise (i.e., social support) for reaching personal goals, for increasing MBSR practice relative to previous weeks, and/or meeting the recommended level of MBSR practice. In addition, an incentive drawing was included in the intervention whereby participants were eligible for a $20 gift card raffle each week, contingent on them handing in their self-monitoring logbooks.
3) *Self-efficacy*: Verbal encouragement to perform regular MBSR practice was also given to participants as part of the weekly telephonic coaching calls. If low self-efficacy or confidence in one's ability to perform regular MBSR practice was determined as a barrier, the investigator encouraged participants to set personal, successive approximation goals (or shaping) whereby the participant started at very easy levels of MBSR practice during early weeks and worked their way up slowly to more frequent MBSR practice over time. The rationale behind this approach was that "success breeds success" and achieving a personal goal, even a small one, would increase self-efficacy and behavioral capability (Bandura, 1997).
4) *Outcome Expectations*: Participants were be reminded of the physical and cognitive benefits of regular MBSR practice during each weekly telephonic coaching call in order to increase the perception of importance and/or commitment to regular MBSR practice. In addition, the weekly incentive gift

card drawing and regular supportive feedback from phone coaching also served to strengthen outcome expectations around regular MBSR practice.

Figure 1. Conceptual model of MBSR adherence based on Social Cognitive Theory.



Theoretically, the SMILE study adherence enhancements should increase each of the SCT-based cognitive, behavioral, and environmental factors outlined above. In turn, this should lead to a high degree of overall MBSR practice time (i.e., adherence to the MBSR practice recommendations). Per Kabat-Zinn (1990), this high degree of time spent practicing MBSR should then lead to increased acceptance of one's current state of mind, followed by regular states of relaxation and reduced chronically stressful states.

Specific Aims

Stress is a clear public health issue in that it is pervasive and contributes to the development of chronic health conditions, such as diabetes and coronary heart disease. Stress can be treated, however, with proper training programs such as MBSR. MBSR has

been shown to be a successful therapy for a variety of stress related ailments, including pain and generalized anxiety. Like most behavior modification programs though, the overall impact of MBSR is thought to be contingent on the amount of exposure to the teachings. In other words, individuals may need to practice MBSR techniques frequently as appropriate in order to maximize their stress reducing benefits both from the actual formal practice, as well as informal application to events and circumstances in daily life.

Interventions to enhance adherence to MBSR practice have not been directly studied or fully described to date in the scientific literature. It is believed that incorporating several behavior modification techniques, such as self-monitoring, telephonic coaching, and financial incentives for program participation in the context of a standard MBSR program, may result in increased MBSR practice time and may improve stress outcomes during the course of the study.

The SMILE study introduced an adherence enhancement intervention package that included self-monitoring, telephonic coaching, and financial incentives applied to participants enrolled in a standard MBSR program. The specific aims of this proposal were to:

1) Quantify, describe, and characterize the pattern of change over 11 weeks for adherence to MBSR practices, as measured by MBSR practice time in the daily logbooks and MBSR adherence scores.

   It was expected that MBSR practice time would increase between week 1 and week 11.

2) Characterize and describe the pattern of change over 11 weeks in MBSR mediating variables, including:
   a. Commitment to engaging in regular MBSR practice
   b. Confidence for engaging in regular MBSR practice
   c. Stress level

It was expected that: (a) commitment to regular MBSR practice would increase, (b) confidence for regular MBSR practice would increase, and (c) stress level would decrease between week 1 and week 11.

3) Characterize the relationship between the overall amount of MBSR practice time and change in stress level during the 11-week study.

It was expected that change in MBSR practice time would be negatively correlated with change in stress level (i.e., as MBSR practice time increased, stress level would decrease) during the 11-week study.

4) Identify common qualitative themes of MBSR practice experiences (i.e., life events, barriers, benefits, preferences, application) that influenced adherence to the MBSR program teachings.

For this qualitative descriptive aim, no a priori expectations were specified.

Chapter III: Methods

The SMILE study utilized an exploratory, single-group, longitudinal research design. This chapter outlines the methodology used to address the specific aims outlined in the previous chapter. The sample, measures, intervention, and analytical procedures are described.

Participants and Setting

The target population of the SMILE study was adult females. Specifically, inclusion criteria were: female sex, age 18 years or older, ambulatory and able to participate in physical activities, willing to adhere to study procedures and follow-up regimens, and ability to communicate in English. Exclusion criteria were: pregnancy, inability to understand study requirements, and cognitively unable to give informed consent. There was a particular interest, though it was not an eligibility requirement, to recruit women with active heart disease to participate because stress management is an important element of the secondary prevention vascular disease events. As described in the recruitment section below, participants were recruited from individuals who were enrolled in the MBSR course associated with a larger parallel study, Lite Hearten,[1] focused on heart disease management.

All intervention procedures took place at the HEARTWOOD Mindfulness Practice Center (Minneapolis, MN) and at the Minneapolis Heart Institute (MHI) Building (Minneapolis, MN). HEARTWOOD is a private practice counseling center located in south Minneapolis and MHI is a multi-specialty cardiovascular services clinic attached to Abbott Northwestern Hospital (Minneapolis, MN).

Recruitment Procedures

The recruitment took place in January 2010. All participants in the MBSR course associated with the stress management intervention arm of an existing study, Lite Hearten, were approached by the SMILE study principal investigator. On the first intervention session of the Lite Hearten study, all participants received a verbal invitation to enroll in parallel in the SMILE study and were given information on study procedures. Several of the participants started after the first scheduled MBSR class and were recruited for the SMILE study at the second session. All participants signed an informed consent form (see Appendix B) for enrollment during their initial MBSR course session. In addition contact information and demographics were also collected (see Appendices C and D).

Measurement Procedures

The following measures were collected: MBSR practice time, MBSR adherence score, commitment and confidence for regular MBSR practice, and stress level. In addition, semi-structured interviews were conducted to qualitatively assess recent stressful life events, barriers to MBSR practice, rewards/benefits experienced as a result of MBSR practice, preferred MBSR techniques, and MBSR application (see Appendices E, F, G, H, and I for all data collection instruments).

As outlined in Figure 2, measures were collected at weekly intervals throughout the 11 week study. Daily MBSR practice time was collected at weekly intervals beginning during week 1 and ending after the completion of week 11. Measures were not collected at enrollment because they required at least some experience with MBSR before

they could be accurately completed. In other words, it would have been unreliable to collect data before the intervention was initiated.

Figure 2. Timeline of measurement instrument administration.

	Week											
	1	2	3	4	5	6	7	8	9	10	11	12
Measure												
MBSR Practice Time												
MAQ Score												
Commitment Rating												
Confidence Rating												
PSS-4 Score												
Qualitative Interview												
Intervention Exposure												

MBSR Practice Time. The amount of MBSR practice was collected through the daily self-monitoring log book that was filled out by participants. Specifically, MBSR practice was quantified by summing daily minutes engaged separately in body scan, sitting meditation, lying meditation, mindful eating, mindful walking, Hatha yoga, and chi-gong. Participants were instructed not to include MBSR practice done during classroom sessions. Session attendance was recorded each week by the SMILE study principal investigator. The total minutes per week and activity-specific minutes per week spent in MBSR practice was reported. Participants who did not turn in a log for a given week were given 0 minutes of MBSR practice that week. In addition, there was a section in the log book for participants to self-rate the quality of each MBSR activity that was recorded in their log.

Mindfulness Adherence Questionnaire. Adherence to MBSR practice and application of MBSR techniques was measured using the Mindfulness Adherence

Questionnaire (MAQ). The MAQ is an 8-item instrument that captures the recalled frequency of typical MBSR techniques (e.g., body scan, sitting meditation, yoga), as well as the frequency of applying such techniques during stressful situations, over the previous week. An index score between 0 and 40 points is calculated for the MAQ by summing the eight 5-point response options. This instrument was designed by the SMILE study principal investigator and was previously used in a pilot test of 12 females. No validity testing has been conduced with the MAQ to date, but a Cronbach's alpha of the MAQ was 0.76, indicating relatively good internal consistency between items (Streiner, 2003).

Commitment and Confidence Rating Scales. Commitment and confidence for engaging in regular MBSR practice was measured using two 0 to 10 point self-rating scales. Specifically, commitment was assessed by asking participants to self-rate from 0 to 10 (with 10 being the most important and 0 being not at all important), how important they perceived that it is for them to practice MBSR for a total of at least 4.5 hours per week (i.e., 45 minutes per day, 6 days per week). Similarly, confidence was assessed by asking participants to self-rate, on a scale from 0 to 10 (with 10 being most confident and 0 being least confident), how confident they are that they would engage in MBSR practice for a total of at least 4.5 hours per week. This rather brief form of assessing commitment and confidence is a practical and commonly used approach for self-assessment of latent variables related to behavior change and is consistent with how Bandura recommends measuring social-cognitive constructs (Bandura, 2006).

Perceived Stress Scale-4. Stress level was measured using the Perceived Stress Scale 4 (PSS-4). The PSS-4 included four items that captured feelings and perceptions about the magnitude of life challenges, as well as personal stress management capabilities

over the previous month (Cohen & Williamson, 1988). An index score between 0 and 16 is created by summing the four 4-point response options. The PSS-4 has firmly established validity and reliability and has been used in several populations. This questionnaire was selected because of its well established psychometric properties and short length in order to minimize response burden, since participants were asked many questions each week during telephonic coaching calls.

Semi-structured Interviews. The SMILE study principal investigator conducted weekly semi-structured interviews with each participant by phone. These interviews were qualitative in nature and included five questions asking participants to describe: (1) recent stressful life events, (2) barriers to MBSR practice, (3) rewards and benefits experienced as a result of MBSR practice, (4) preferred MBSR techniques, and (5) examples of how MBSR techniques were implemented and applied in response to stressful challenges in their lives. Verbatim responses and dialogue from each interview was transcribed into electronic transcripts. A more detailed description of how qualitative themes were identified is reported in the Data Analysis section below.

Procedure Summary

The intervention procedures included MBSR classroom sessions (with an all day silent retreat), cardiac support group sessions, self-monitoring using MBSR log books, weekly telephonic coaching phone calls, and weekly raffle incentive drawings. Each of these interventions is described in more depth below. A timeline of all intervention procedures and when they occurred is outlined in Figure 3.

Figure 3. Timeline of intervention activities.

	Week											
	1	2	3	4	5	6	7	8	9	10	11	12
Intervention												
Support Group Session												
MBSR Session												
MBSR Retreat												
MBSR Self-Monitoring												
Telephonic Coaching												
Incentive Drawings												

Intervention

Cardiac Support Group. The stress management intervention for the SMILE study combined a standard 8 week MBSR program (with an all day retreat) interspersed with 4 weeks of cardiac support group. The purpose of the cardiac support group was to help participants with cardiovascular disease adjust to their diagnoses and focused on topics that enabled them to understand more about their condition by providing additional resources. This support group provided a way for participants to process their experiences and helped to reduce the physical and emotional isolation that is common when recovering from a cardiac event. This support group was also offered to non-cardiac SMILE study participants as an additional means of social support. All participants were expected to continue practicing MBSR during weeks of cardiac support.

The four cardiac support group sessions were based on the book, *From the Heart: A Woman's Guide to Living Well with Heart Disease* (Kastan, 2007). At the first support group session this book was distributed, an overview was given, and the introduction

portion of the book was reviewed. The following support group sessions focused on three sequential sessions of the book: (1) Beginning the Recovery Process: The First Steps, (2) Rebuilding Your Sense of Self, and (3) Negotiating the Outer World (see Appendices J, K, L, and M for session discussion guides). The group context aided participants to develop effective coping mechanisms through story sharing.

MBSR. The MBSR portion of the stress management intervention encouraged participants to become more aware of their present surroundings and experiences (Kabat-Zinn, 1982). As is standard in MBSR program design, the course was conducted over eight sessions in a group format (Kabat-Zinn, 1990; Salmon, Santorelli, Sephton, & Kabat-Zinn, 2009). The program activities included discussions and demonstrations in context of weekly group sessions in a classroom setting, interspersed with daily practice of MBSR techniques away from the classroom (recommended 6 days per week for 45 minutes per day, or 4.5 hours per week). In addition, a 7-hour, day-long retreat of mindfulness was included, which allowed participants to further practice and crystallize their mindfulness skills.

The MBSR program was taught by a middle-aged female who is a Masters level psychologist with over 16 years of experience in MBSR training and in marriage-family therapy. Participants were taught several formal meditation techniques including body-scan, sitting/lying meditation, mindful eating and walking, and Hatha yoga. The general lesson plan was as follows:

- MBSR Session 1 – Introduction: This session focused on an introduction to the program principles, a discussion of the foundation of mindfulness

and a general acceptance of one's mind/body, and an introduction to body scan meditation.

- MBSR Session 2 – Patience: In this session participants learned how to work with their own perceptions, wandering minds, and continued practice of body scan meditation.
- MBSR Session 3 – Non-striving: In this session, awareness was attained using breathing meditation, lying yoga, and an exercise exploring attention versus inattention was introduced.
- MBSR Session 4 – Non-judging: Participants completed an exercise that had them examine responding versus reacting, along with sitting meditation, standing yoga, and a discussion about research on stress and stress resiliency over time.
- MBSR Session 5 – Acknowledgment: In this session (halfway point), group reflections were discussed in small and large groups and guided sitting meditation was practiced.
- MBSR Session 6 – Letting it be: Participants worked on skillful communication, discussed the difference between difficulty versus entering and blending, loving kindness, and walking meditation was introduced. A daylong retreat followed this MBSR session later that week.
- Daylong Retreat – The MBSR silent 7-hour day retreat consisted of lead meditations, gentle movement exercises, and group sharing. The general schedule entailed the following: (1) introduction, (2) an awareness of breathing, (3) lying yoga, (4) body scan meditation, (5) walking

meditation, (6) sitting meditation, (7) lunch and rest, (8) yoga, (9) sitting meditation, (10) walking meditation, (11) sitting meditation, (12) walking meditation, (13) loving kindness meditation, and (14) group discussion and wrap up.

- MBSR Session 7 – Trust and self-reliance: In this session, along with sitting meditation, participants learned about mindful movement, trust and self-reliance, discussed ways to apply meditation and incorporate mindfulness in everyday life situations.
- MBSR Session 8 – Reflection: In this final session, participants continued their work with mindful movement, sitting meditation, and learned ways on how to maintain regular MBSR practice habits over a lifetime. The program ended with a course review and group reflection of progress.

MBSR Adherence Enhancements. In addition to the standard MBSR program, three program components were added to improve overall adherence to MBSR practice time. These adherence enhancements were based on Bandura's (1986) SCT as previously outlined in the conceptual framework. The adherence enhancements included self-monitoring, telephonic coaching, and a financial incentive.

Self-monitoring. All participants were given a log book and instructed to track the frequency and duration of MBSR practice occurring outside of the scheduled classroom sessions. A new log book was provided to participants each week upon attendance to their intervention session. Additional log books were also provided with the MBSR program and SMILE study materials given at the time of enrollment and were made available upon request. The log books were formatted in a checkbook style with a front

cover and removable logs in calendar format which include eight available days to record data (one per day for one full week). Participants submitted their log book from the previous week at the start of each session. Participants who are unable to attend a session continued to record their MBSR practice in their extra log books and turned in the previous week's worth of data at the following session. An example of instructions provided to participants in each MBSR log book and the pages to record daily MBSR activities are included in Appendix E.

Telephonic Coaching. Participants received one follow-up telephone call that was prescheduled with participants each week over the course of 11 weeks. Each call was designed to last about 20 minutes and was led by the SMILE study principal investigator. Calls were tailored to participant interests, but followed a general structure that included: (1) completion of weekly assessments (described in the Measures section), (2) progress review on MBSR practice during the previous week, (3) supportive feedback for regular MBSR practice and/or meeting personal goals, (4) reminders of the physical and cognitive benefits of regular MBSR practice, and (5) problem-solving advice to address barriers to MBSR practice. Problem-solving strategies included identifying barriers, brainstorming solutions, and solution implementation planning per the guidelines outlined by Pichert, Snyder, Kinzer, and Boswell (1992).

Participants were also encouraged to continue practicing MBSR techniques daily. At the end of each call, the next call for the following week was scheduled. If a participant missed a scheduled call, they were contacted up to 2 additional times before the next MBSR classroom session (a total of 3 telephone call attempts were made per week). For participants who were unable to be reached during any given week, the

SMILE study principal investigator continued to call them to reschedule the next telephone coaching call up to 3 times each week. Also, if a participant was absent during the previous session, they were reminded to return to the following MBSR session. A call log was used to track phone call attempts and encounters.

Financial Incentive. Upon submitting their log books at the beginning of each week's classroom session, each participant was entered into a $20 Target retail store gift card raffle (note that this occurred at both MBSR and support group sessions). Eligibility for this drawing was contingent on submission of the previous week's log book, regardless of the amount of time spent or frequency of MBSR home practice. If participants submitted more than one week's worth of data (i.e., multiple log books), they were still only eligible for one entry in the current week's drawing. In other words, only one log book from their MBSR practice from the previous week was included in the incentive drawing (i.e., only one chance to win per week), but they were still encouraged to turn in all completed log books. For the incentive prize drawing, the SMILE study principal investigator placed the log books in a box and the box was vigorously shaken, allowing the log books to fully mix. One log book was then drawn randomly from the box, the winner was announced, and the gift card incentive was immediately presented.

Human Subjects Considerations

Risks to Subjects. MBSR has not been shown to result in known psychological harm, therefore the overall risk of participating in the SMILE study was considered minimal by the investigators and both the University of Minnesota and Abbott Northwestern Hospital Institutional Review Boards. Possible risks included: expression of feelings during personal disclosures making participants feel uncomfortable, feeling

awkward when assuming positions of relaxation and with stretching in the company of others, and/or feeling deprived if not drawn for an incentive gift card. There are slight risks associated with the physical activities that are involved in some of the MBSR techniques, particularly yoga. Common musculoskeletal injuries related to physical activity include: sprained ankles, pulled muscles, or, in severe cases, bone fractures. Data privacy was also a risk to subjects in this study because they may have disclosed personal health information to the principal investigator.

Protection against Risks. All subjects completed the study informed consent whereby the risks outlined above were reviewed and discussed thoroughly. All SMILE study procedures were approved in advance by the University of Minnesota and Abbott Northwestern Hospital Institutional Review Boards (see Appendices N and O) via expedited review. The SMILE study principal investigator and co-investigator are registered nurses and were able to appropriately refer participants to their medical provider if a health concern was suspected at any time. The incentive gift card associated with the intervention was of modest monetary value with a relatively high chance of participants winning at least one incentive prize over the course of the 11 weeks it was available. All transcribed assessment information was stored in secured data files with permission granted only to study staff. The principal investigator oversaw all data management. All forms were identified with a unique ID number only and are kept in a locked file with limited access. No adverse events were observed in the SMILE study.

Data Analysis

Descriptive statistics were reported for all measures. All analytical procedures were conducted using the Statistical Package for the Social Sciences (Version 15, 2006, Chicago, IL). Sample size calculations were not done for this study because it was a pilot study and, as such, the results obtained will be used to inform the design (and power calculations) for a larger trial. Of note, four participants were enrolled in the SMILE study after the initial study session and during calendar week 2. These participants received the same number of sessions (they were given an initial "make-up" session between the normal study sessions during week 1 and week 2), but one less calendar week of total exposure to the adherence intervention. Their measures technically began being collected during calendar week 2 of the study, but for analytical purposes, this initial data collection timepoint was treated as both week 1 and week 2. In other words, these participants' measures collected during week 2 were also imputed as their week 1 values in order to calculate change scores at the start and end of the study.

Aim 1. In Aim 1, the objective was to quantify and characterize the pattern of change over 11 weeks for adherence to MBSR practices, as measured by MBSR practice time in the daily logbooks and the MAQ score. A Wilcoxon signed ranks test was used to generate an effect size estimate for the week 1 to week 11 change scores in each of these dependent variables, separately. The Wilcoxon test was used as a non-parametric alternative to a paired t-test due to the inability to assess whether data was normally distributed due to the small sample size. To aid in interpretation of the results, a Cohen's *d* effect size estimate was calculated (for repeated measures) for each of these variables (Cohen, 1988). The Cohen's *d* represents the difference between the pre and post scores

in pooled variance units, and after accounting for the correlation between pre and post scores in a repeated measures sample. Cohen generally considers an effect size of .20 as small, .50 as moderate, and .80 as large.

Aim 2. In Aim 2, the objective was to characterize the pattern of change over 11 weeks in MBSR mediating variables, including commitment to regular MBSR practice, confidence for regular MBSR practice, and perceived stress level. Similar to the analytical approach in Aim 1, a Wilcoxon signed ranks test was used to generate an effect size estimate for the week 1 to week 11 change scores for each of these dependent variables, separately. As outlined in Aim 1, a Cohen's *d* effect size estimate was also calculated for each of these variables.

Aim 3. In Aim 3, the objective was to characterize the relationship between change in stress level and: (1) overall amount of logged MBSR practice time, and (2) MAQ score at week 11. An X-Y plot of the total logged MBSR practice time by stress level change score, as well as the 11-week MAQ score by stress level change score, was created. Change in stress level was calculated by subtracting the week 1 PSS-4 score from the week 11 PSS-4 score. An examination between these variables was visually assessed since a formal dose-response statistical analysis would have been unreliable given the small sample size. A Spearman's correlation for both of these relationships was reported for descriptive purposes to help characterize the direction and strength of the correlation. To characterize the relationship between MBSR adherence and change in stress over the 11-week study, a plot was also created for each individual participant, displaying their MAQ score, logged MBSR practice time, and PSS-4 score each week over the 11 weeks. Similarly, these individual plots were visually, qualitatively analyzed

to detect common patterns, particularly in regard to whether or not MBSR practice and stress level change was in parallel over time.

Aim 4. In Aim 4, the objective was to identify common qualitative themes of MBSR practice experiences (i.e., life events, barriers, benefits, preferences, application) that influenced adherence to the MBSR program teachings. Using an inductive approach to qualitative content analysis with interpretative overtones, a fundamental qualitative description was created based on a standardized research principles modeled by Sandelowski (2000). A basic qualitative description was the most suitable approach since the variables to be studied were pre-selected (i.e., semi-structured interview questions) based on assumptions supported from the current literature. Using a descriptive method helped to ensure valid inferences, minimizing the risk that the SMILE study principal investigator would extrapolate conclusions beyond the data. In order to maintain "epistemological credibility" (Thorne, Kirkham, & MacDonald-Emes, 1997, p.170), an interpretative qualitative description of the data that was categorical, clearly interpretative, and required minimal theoretical depiction of the data was implemented (Sandelowski, 2000). It is important to acknowledge that the investigator, experts, and research team's transformation and description of the data was influenced by their personal perceptions and experiences (Sandelowski, 2000), thus producing a final product that was enriched by the shared experiences of the participants and researchers.

The SMILE study PI conducted qualitative semi-structured interviews each week and during these interviews, the investigator ensured that the statements made by participants were accurate and clearly understood using the member checking technique outlined by Polit and Beck (2008). These interviews were transcribed verbatim each

week. There were several instances that required the investigator to ask participants to clarify their statements made in the previous week's interview, prior to beginning the phone interview for the subsequent week. This technique was used only when the investigator was unable to understand feedback made by participants during the transcription process of the previous week's interview. After the transcripts were completed, the investigator ensured accuracy by listening to audiotapes and comparing them to the transcribed data.

An experienced qualitative researcher was consulted prior to and during the qualitative analysis stage. Specifically, the investigators and qualitative and MBSR content experts completed the qualitative descriptive analysis. This step-by-step process of analyzing narrative text was used to code the data to identify themes, categorize the primary patterns, and ultimately describe common meanings using composite analysis (Sandelowski, 1995).

In the first steps of the process, the principal investigator re-read the interview transcripts several times to become familiarized with the content (Sandelowski, 1995). The investigator then met with an MBSR content expert and a qualitative analysis expert for final review of these data. All semi-structured interview responses were printed and grouped by question. The investigator and experts organized responses from all of the participants for each question and placed them into separate piles.

The investigator and experts then read the participant responses to each question independently, wrote interpretative summaries, and identified common themes and the content that supported them (Sandelowski, 1995). Once the investigator and experts reviewed all of the transcripts and identified themes containing pertinent concepts, the

group came together to further clarify the core themes (Field & Morse, 1991). Group analysis of the transcripts and referring back to the original transcripts to resolve interpretive disagreements allowed the investigator and experts to arrive at consensus on the common identified themes. After the transcripts were reviewed by the group to clarify any interpretive dissimilarity, the data-driven themes were categorized, coded/labeled, and patterns linking the themes were characterized through the process of comparing and contrasting (Polit & Beck, 2008).

The investigator and experts agreed that the best way to analyze the responses from the question, *"Which MBSR techniques do you like most?"* was to count the total number of responses for each MBSR technique (i.e., body scan, sitting, meditation, lying meditation, mindful eating, mindful walking, Hatha yoga, chi-gong). This method of descriptively reporting the results of the data facilitated the ability to identify patterns within the data (Sandelowski, 2000).

In the final description of the qualitative data, a senior University of Minnesota investigator with extensive experience in qualitative research was consulted to ensure that the patterns were appropriately identified and articulated, linking common themes and describing shared meanings from the experiences (Wojnar & Swanson, 2007). This consulting expert validated that best practice qualitative data analysis methods were used to create the final SMILE study qualitative conclusions.

Quality and rigor were ensured throughout the process of data collection and analysis by adhering to Whittemore and colleagues (2001) principles of creditability, authenticity, criticality, and integrity, which is similar to Sandelowski's (1993) concept of trustworthiness. Whittemore et al., (2001) describe credibility as the conscious effort to

establish confidence in an accurate interpretation of the meaning of the data. Therefore it was important to make certain that the results of the research reflected the experiences of each participant in a believable way. Measuring authenticity was similar to credibility, in that they both involve the portrayal of research that reflects the meanings and experiences that were perceived by the participants (Sandelowski, 1993). Accurate transcription and review of the data by the experts and research team kept the information authentic and credible to minimize any distortion of the data that would have threatened descriptive and interpretative validity (Whittemore, Chase, & Mandle, 2001).

Recognizing that different researcher may have different assumptions, experiences, and varying interpretations that could potentially affect the criticality and integrity of the research (Whittemore, Chase, & Mandle, 2001), a process employing open inquiry, reflexivity, and critical analysis was implemented to minimize this risk. Examples of how these criteria were meet included writing and talking in language that was easily understandable to the participants, clarifying with participants throughout the interview process to gain a greater understanding of individual meanings, and by consulting with experts in the field throughout the data collection and analysis processes. The use of this method assured that the interpretation of the data was valid and that conclusions were grounded (Johnson, 1999). An audit trail of the qualitative data was also implemented by recording interviews, keeping all field notes, and documenting each stage of the qualitative analysis process (Polit & Beck, 2008).

Chapter 4: Results

This chapter describes the findings from the SMILE study. It starts with a summary of the study sample characteristics and attendance at the weekly intervention sessions (i.e., MBSR classes and support group meetings). In Aim 1, estimates of change in logged MBSR practice time and MAQ score between weeks 1 and 11 are outlined. Similarly, estimates characterizing week 1 to week 11 change in commitment, confidence and stress level are described in Aim 2. In Aim 3, the association between change in stress level and: (1) total logged MBSR practice time, and (2) week 11 MAQ score are estimated. Included in this is a plot of each individual participant's logged MBSR practice time, MAQ score, and stress level by week (with associated visual analysis). Finally, the findings from the qualitative semi-structured interviews are summarized in Aim 4.

Sample Characteristics

Twelve participants were successfully recruited and enrolled in the SMILE study. As outlined in Table 1, the sample primarily comprised White, married, well educated, females. Most participants were middle-aged with some geriatric (i.e., over age 65) participants. Fewer than half of the sample worked full-time. Four participants had heart disease and were concurrently enrolled in the Lite Hearten study. One participant withdrew from the study after their first session due to a philosophical disagreement with the MBSR teachings in that they felt MBSR conflicted with their religious beliefs. Another participant was unable to participate in the study after the fourth week of the study due to an extended hospitalization. A total of 10 enrolled participants successfully

completed both baseline measures (i.e., week 1) and follow-up measures (i.e., week 11) for the study.

Table 1. Descriptive characteristics of enrolled SMILE study participants.

	N=12
Age (y)	
25-34	3 (25%)
35-44	0 (0%)
45-54	2 (17%)
55-64	4 (33%)
65-74	3 (25%)
Married or living with partner	11 (92%)
College degree	10 (83%)
White race/ethnicity	11 (92%)
Employment	
Full time	5 (42%)
Part time	2 (17%)
Homemaker	1 (8%)
Retired	2 (17%)
Other	2 (17%)
Annual household income	
Less than $10,000	0 (0%)
$10,000 – $19,999	2 (17%)
$20,000 – $29,999	0 (0%)
$30,000 – $39,999	4 (33%)
$40,000 – $49,999	0 (0%)
$50,000 – $75,000	1 (8%)
More than $75,000	5 (42%)

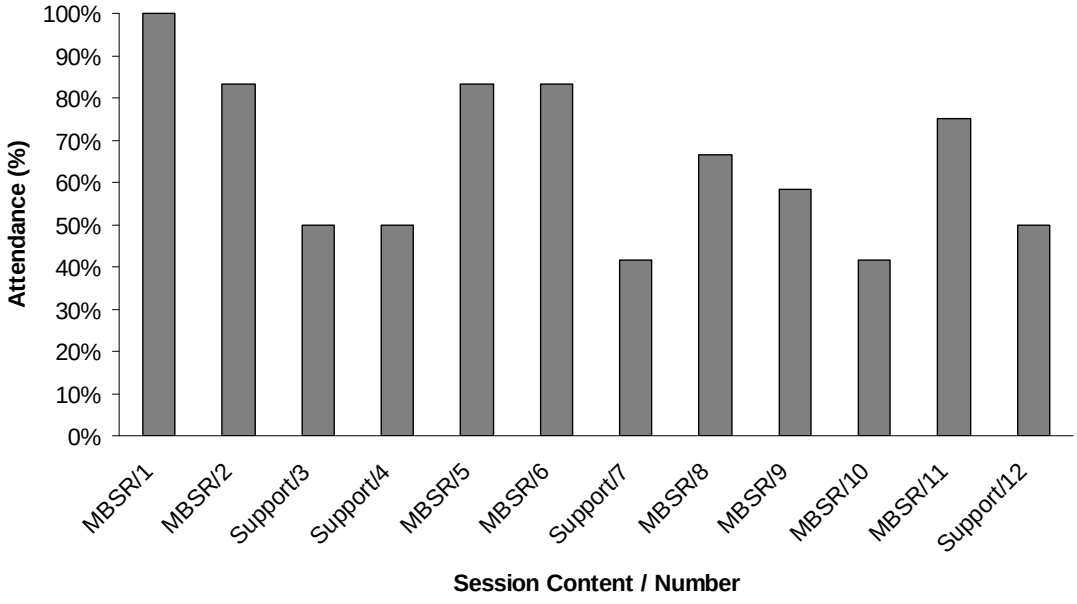
Values are reported as frequency counts (% of all enrollees).

Session Attendance

Session attendance is presented by percentages in chronological order in Figure 4. As expected, MBSR sessions clearly had the highest attendance rate relative to the

support group sessions, with less than half the sample typically attending support group sessions. There was, however, a general pattern of lower session attendance over time for both MBSR and support groups. Using the standard definition of MBSR program completion established by Salmon and colleagues (2009) (i.e., attending ≥5 of the 8 available MBSR sessions), nine of the original 12 enrolled participants completed the program. Among the nine program completers, mean ±sd number of MBSR sessions attended (not counting the retreat) was 7±1.5. Among all 12 enrollees, the mean number of MBSR sessions attended was 6±2.6. Eight participants attended the all-day MBSR retreat at the end of study week 9. Reasons for session non-attendance were not systematically tracked.

Figure 4. Participant session attendance over time in the SMILE study.



Adherence Intervention Exposure

Exposure to the adherence enhancement intervention included the number of MBSR self-monitoring logs, telephonic coaching calls, and incentive gift card drawings completed. Among all 12 enrollees, the mean number of MBSR self-monitoring logs submitted was 8.5±4.1, the mean number of telephonic coaching calls completed was 9.2±3.5, and the mean number of incentive gift card drawings participated in was 5.2±2.8. Among the 10 enrollees who did not withdraw from the study, the mean number of MBSR self-monitoring logs submitted was 10.1±1.7, the mean number of telephonic coaching calls completed was 10.6±0.5, and the mean number of incentive gift card drawings participated in was 6.1±2.0. The average amount of time spent on each telephonic coaching call was not recorded.

Aim 1

The research question for Aim 1 was "Does logged MBSR practice time and MAQ score change between week 1 and week 11?" Adherence to MBSR practice was characterized using two outcomes: first, from the total MBSR practice time in participants' logbooks; then from participants' MAQ scores. Specifically, the difference between study week 1 and study week 11 were statistically compared for both of these outcomes (separately). For analytical purposes, week 1 was generally considered baseline and week 11 considered the post-program follow-up. As outlined in Table 2 below, both the logged MBSR practice time (n=8 participants with complete data at both time points) and MAQ score (n=10 participants with complete data at both time points) went up between study week 1 and study week 11. The MAQ score increased significantly (mean change ±sd = 8.6±6.1, effect size of 2.29, p = .01).

Table 2. Summary of changes in MBSR adherence.

	Baseline (Week 1)	Follow-up (Week 11)	Baseline to Follow-up Change	Effect size
Logged MBSR practice time (min/wk) *	238.1 ±114.0	272.9 ±124.6	34.8 ±90.4 (p=.38)	.55
MAQ score (0-40 pts) **	17.7 ±4.5	26.3 ±7.7	8.6 ±6.1 (p=.01)	2.29

Values are reported as mean ±sd
* n=8
** n=10

For descriptive purposes, the mean levels of logged MBSR practice time and MAQ score by week are displayed in Figures 5 and 6 below. This includes all available data from the entire sample (versus just those with data from study week 1 and study week 11). Over time, the general pattern evident in both Figures was that of modest attrition, more variability, and modest increases in MBSR practice. In terms of specific MBSR activities that comprise the total MBSR practice time metric (i.e., body scan, sitting meditation, lying meditation, mindful eating, mindful walking, Hatha yoga, and chi-gong), the rank ordered cumulative amount of hours (over 11 weeks) engaged in each were: body scan (127 hours), sitting meditation (110 hours), Hatha yoga (72 hours), mindful walking (39 hours), mindful eating (27 hours), lying meditation (21 hours), and chi-gong (0 hours). Note that chi-gong was not covered by the instructor in the MBSR class as part of the SMILE study.

Figure 5. Logged MBSR practice time over 11 weeks in the SMILE study.

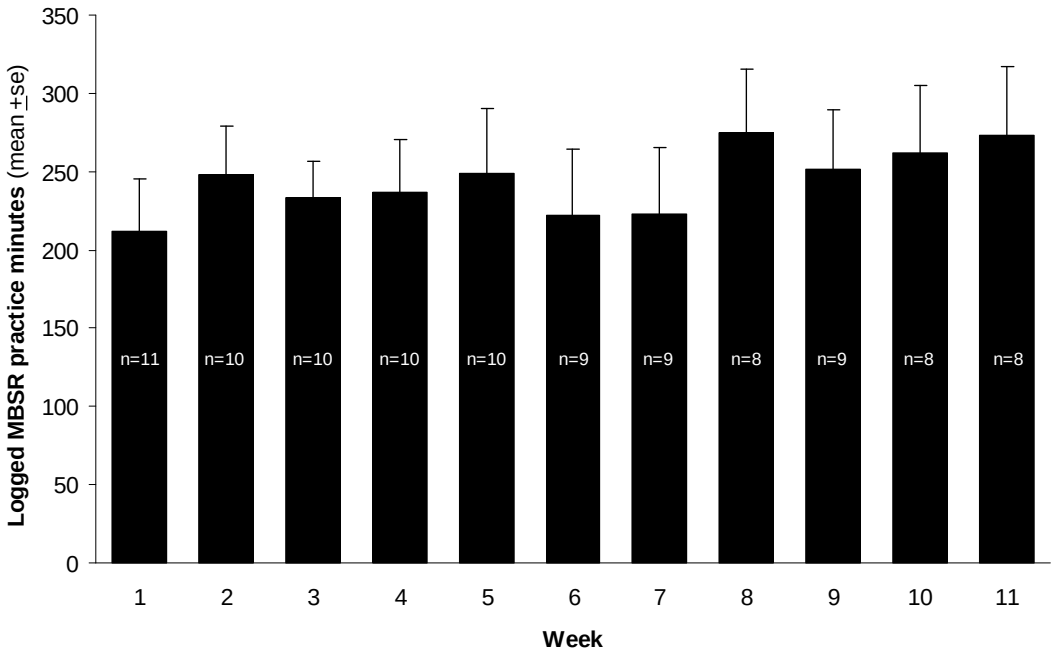
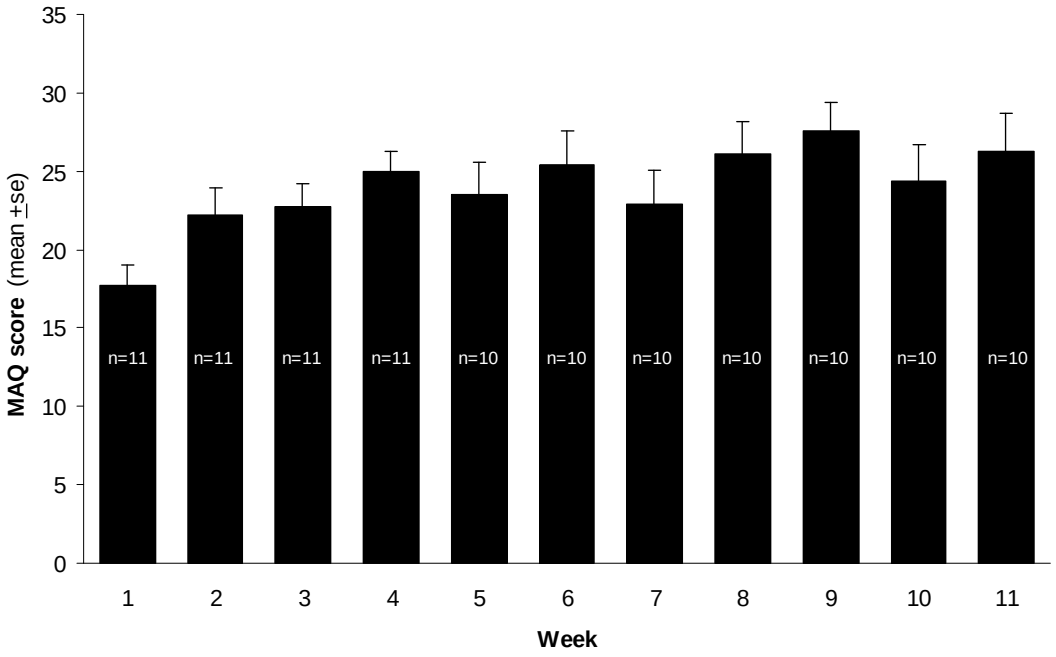


Figure 6. MAQ score over 11 weeks in the SMILE study.



Aim 2

The research question for Aim 2 was "Does commitment, confidence, and stress level change between week 1 and week 11?" Suspected mediators of MBSR practice, including commitment and confidence for regular MBSR practice, as well as perceived stress level, were examined over time similar as was done for MBSR adherence measures. Specifically, the difference between study week 1 and study week 11 were statistically compared for all three of these outcomes (separately). As outlined in Table 3 below, the mean of all of these variables (n=10 participants with complete data at both time points) numerically improved slightly between study week 1 and study week 11, but none did so significantly.

Table 3. Summary of changes in putative MBSR mediators (n=10).

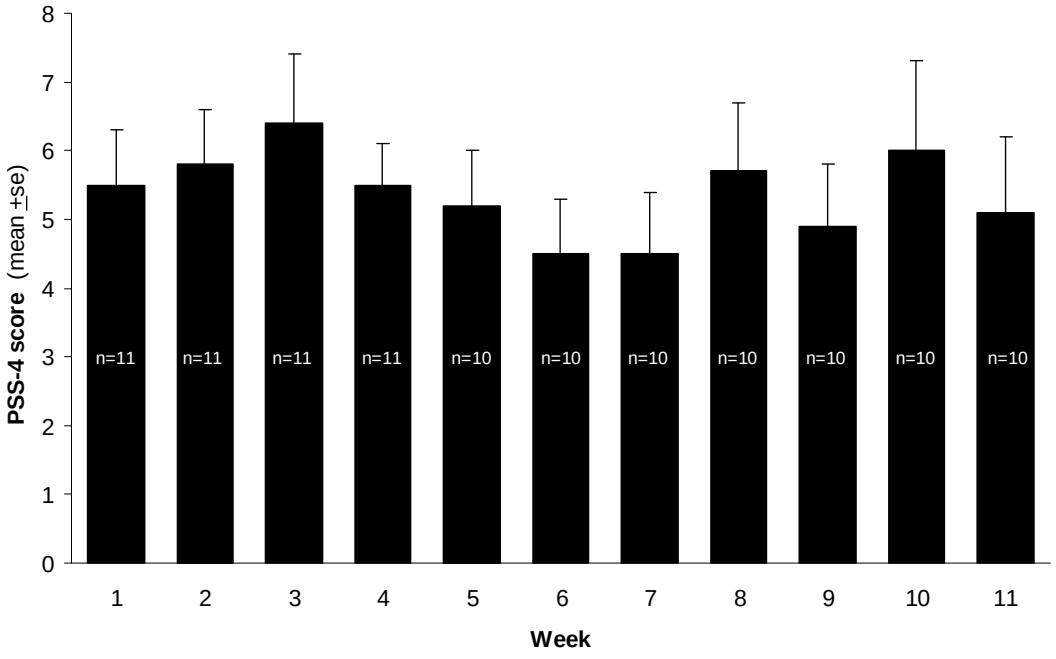
	Baseline (Week 1)	Follow-up (Week 11)	Baseline to Follow-up Change	Effect size
Commitment rating (0-10 rating)	8.4 ±1.1	8.7 ±1.2	0.3 ±1.1 (p=.44)	.39
Confidence rating (0-10 rating)	6.6 ±1.8	6.9 ±1.6	0.3 ±1.7 (p=.72)	.25
PSS-4 score (0-16 points)	5.2 ±2.6	5.1 ±3.4	-0.1 ±3.1 (p=.93)	.05

Values are reported as mean ±sd.
For all ratings, higher scores equal higher levels of the measured construct.

For descriptive purposes, the mean perceived stress level by week is displayed in Figure 7. This includes all available data from the entire sample (versus just those with data from study week 1 and study week 11). Over time, there was no strong pattern of perceived stress level change, but there were some indications that stress reduction may have reached its lowest point in the middle of the study. Note that similar descriptive

graphs were not created for commitment or confidence rating because they remained largely stable throughout the 11-weeks of the SMILE study.

Figure 7. Perceived stress level over 11 weeks in the SMILE study.



Aim 3

The research question for Aim 3 was "Is overall MBSR practice time associated with change in stress level during the 11-week study?" The association between MBSR practice time and change in stress level during the 11-week study was also examined. Specifically, MBSR practice time was modeled using two different measures; total logged MBSR practice time and the MAQ score during week 11. An X-Y plot of each of these associations is outlined in Figures 8 and 9 below. Increased MBSR practice time was visually associated with decreased stress level in both models. The Spearman's correlation was strongest and statistically significant for the model using the MAQ score as a predictor of decreased stress ($r=-.69$, $p=.03$).

Figure 8. Total logged MBSR practice time and change in stress level over 11 weeks.

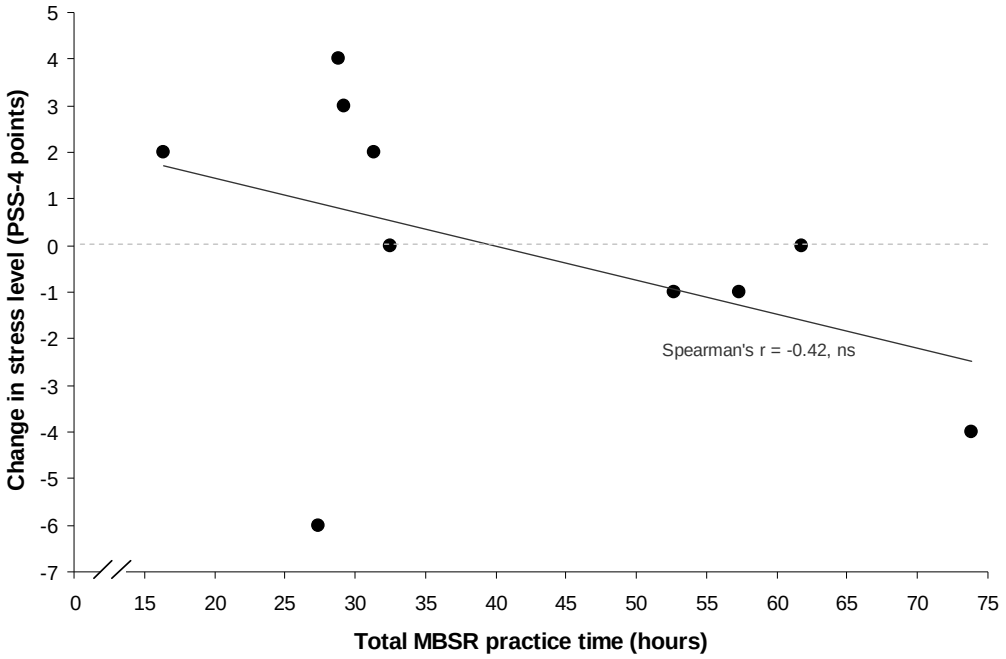
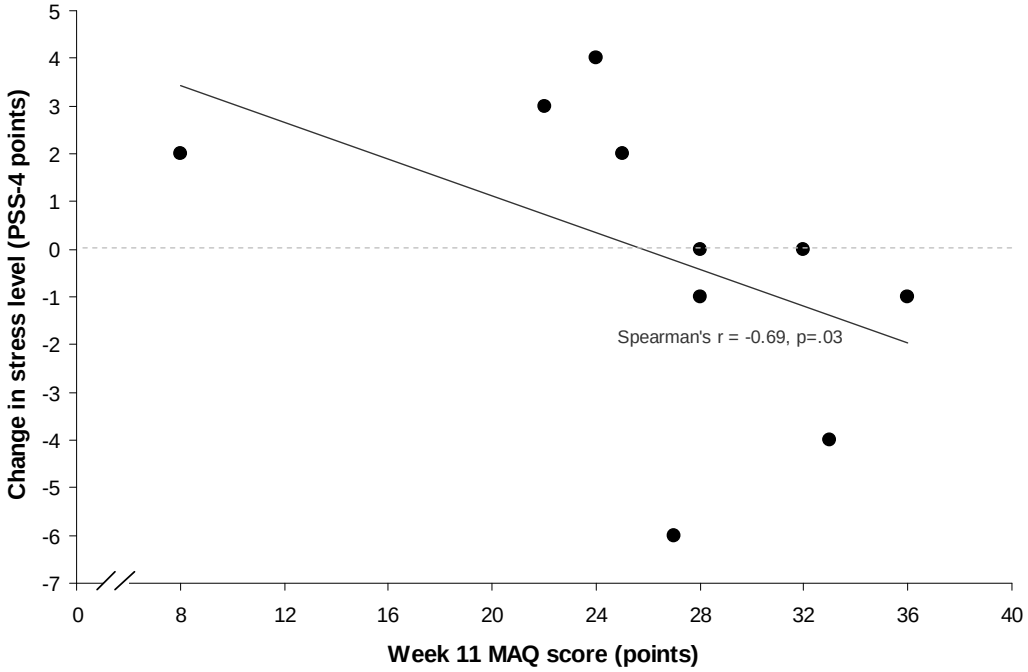


Figure 9. MAQ score at study week 11 and change in stress level over 11 weeks.



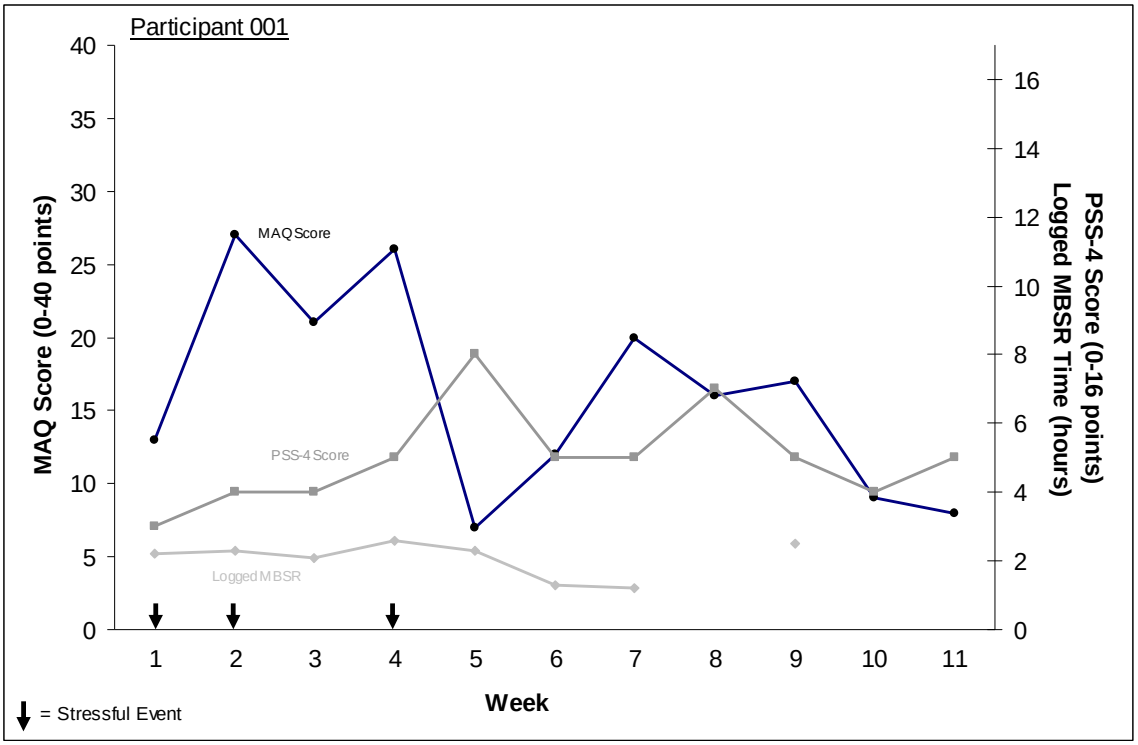
Individual Plots. In addition to the group level statistical analyses described above, each individual participant's logged MBSR practice time, MAQ score, and stress level was plotted. These individual plots were created to visually detect more detailed weekly patterns in each of these three variables. This was primarily done to identify the degree to which MBSR practice and stress changed in parallel from week to week during the active intervention. Each participant's plot is displayed in Figures 10 through 20 below, along with a description of the visual analysis for it.

In addition, stressful life events were indicated for each participant in each plot as they were reported each week (note that there was no measurement for the degree of intensity of any specific stressful life event beyond the rating of overall stress level in the PSS-4). In order to maintain the confidentially of enrolled participants due to the small sample size of the SMILE study, stressful events were not listed for each individual, but rather summarized to give the reader a sense of common, ongoing stressors affecting the group. Examples of stressors included health issues included ongoing hip, back, and chest pain, urgent care visits, hospitalizations, surgery, management of congestive heart failure, atrial fibrillation, anemia and having a miscarriage. In addition, school pressures and residential concerns, which included purchasing and selling/buying a home and moving was reported. Further, many participants reported that planning family events/social obligations (i.e., family reunions, birthday parties, doing childcare) and caring for others during times of spousal unemployment/illnesses, friends' illnesses/deaths, and disagreements with spouse, adult children, and grandchildren were also perceived as stressful events. Last, ongoing stress related to work included job loss, spousal job loss, job searching, initiation of personal business, financial concerns, work travel, increasing

responsibilities at work, management and lack of collegial support and difficulties with new technologies, which affected their ability to practice MBSR on a regular basis.

Participant 001. Logged MBSR practice time for participant 001 was relatively stable until study week 5, where it began to decline (see Figure 10). This seemed to follow a stressful life event during study week 4. The pattern of logged MBSR practice time seemed to parallel the MAQ score over time in that it also declined during study week 5.

Figure 10. Weekly logged MBSR practice time, MAQ score, and PSS-4 score for participant 001.



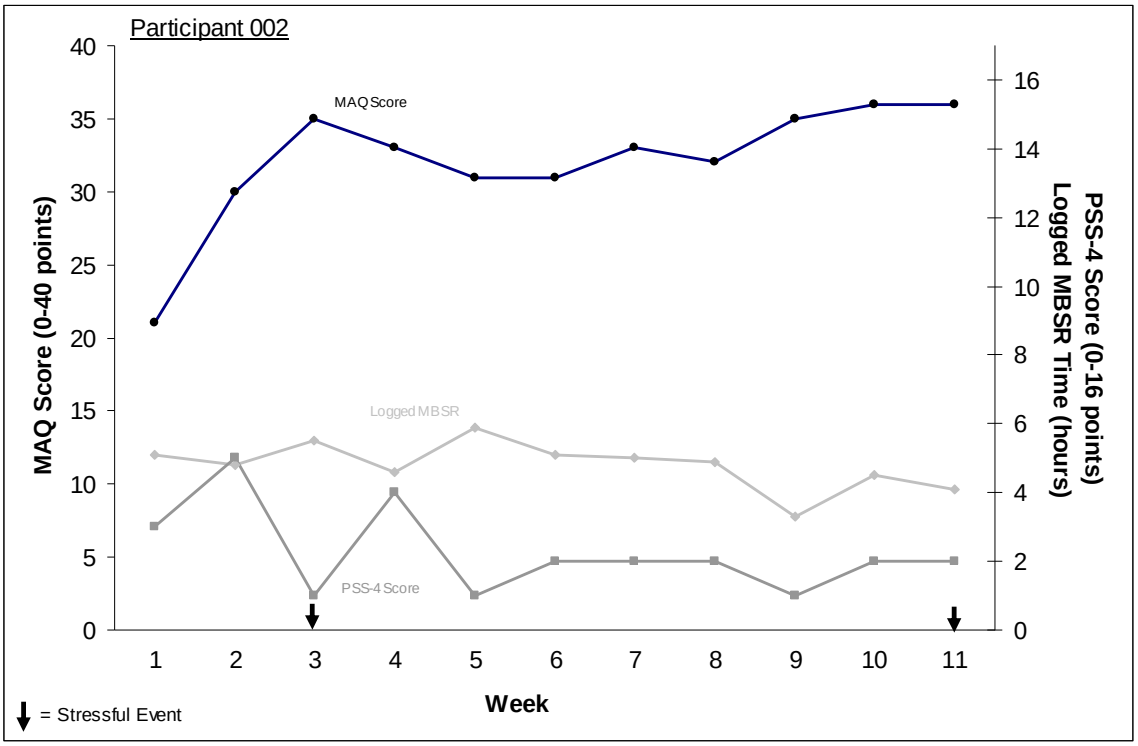
MAQ: higher scores equal greater MBSR practice
PSS-4: lower scores equal less stress

Accordingly, PSS-4 score began to rise sharply at this same time as well. Stress level seemed to then improve somewhat in the latter half of the study and MAQ score generally was at the level observed during study week 1 during this timeframe as well.

Generally speaking, stress level improved in the later half of the study while self-reported MBSR practice declined.

Participant 002. Logged MBSR practice time for participant 002 was relatively stable until study week 9, with a moderate decline followed by recovery (see Figure 11). The MAQ score increased rapidly during the first three weeks of the study and remained quite high throughout the remainder of the study. The pattern of logged MBSR practice time seemed to be inconsistent with the MAQ score over the first three weeks of the study.

Figure 11. Weekly logged MBSR practice time, MAQ score, and PSS-4 score for participant 002.

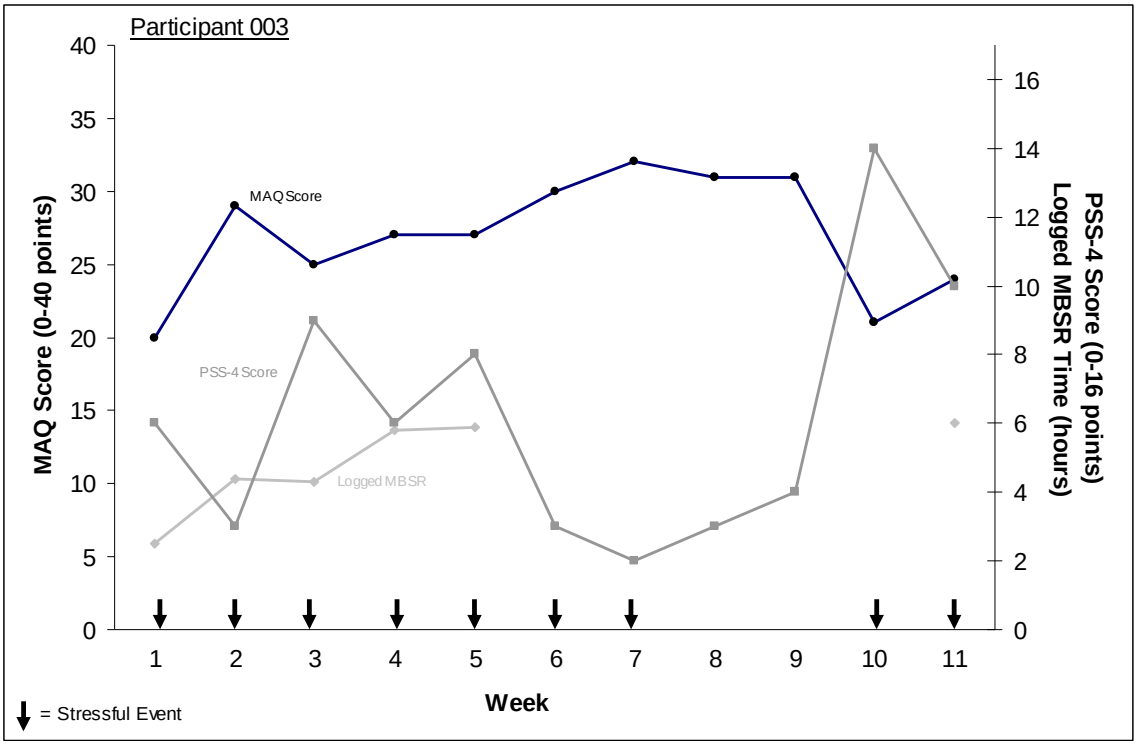


MAQ: higher scores equal greater MBSR practice
PSS-4: lower scores equal less stress

Unexpectedly, the PSS-4 score dropped sharply at the same time as a stressful life event during study week 3, but recovered and generally remained steadily low throughout the remainder of the study. Generally speaking, the stress level remained stable while self-reported MBSR practice time increased over the 11 weeks.

Participant 003. Logged MBSR practice time for participant 003 steadily increased until study week 5, where tracking stopped until the final week of the study (see Figure 12). The pattern of logged MBSR practice time seemed to parallel the MAQ score over the first five weeks, and the MAQ score continued to increase until week 9, where it sharply declined.

Figure 12. Weekly logged MBSR practice time, MAQ score, and PSS-4 score for participant 003.

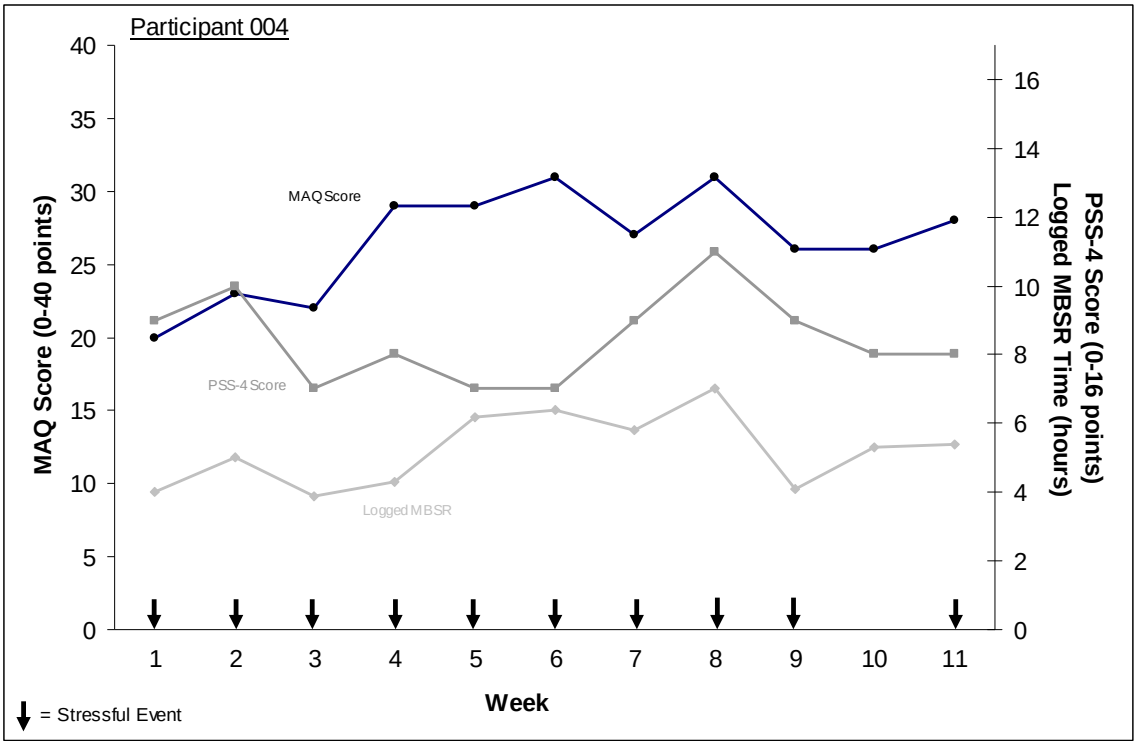


MAQ: higher scores equal greater MBSR practice
PSS-4: lower scores equal less stress

Although the participant regularly reported stressful life events during the study, the PSS-4 score dropped suddenly after week 5 and remained low until the final two weeks of the study where additional stressful life events seemed to reoccur. Generally speaking, stress level increased while self-reported MBSR practice time decreased, during the last 2 weeks of the study.

Participant 004. Logged MBSR practice time for participant 004 gradually increased until study week 9, and then declined to a level near week 1 (see Figure 13). The pattern of logged MBSR practice time ran in very close parallel to the MAQ score over time.

Figure 13. Weekly logged MBSR practice time, MAQ score, and PSS-4 score for participant 004.

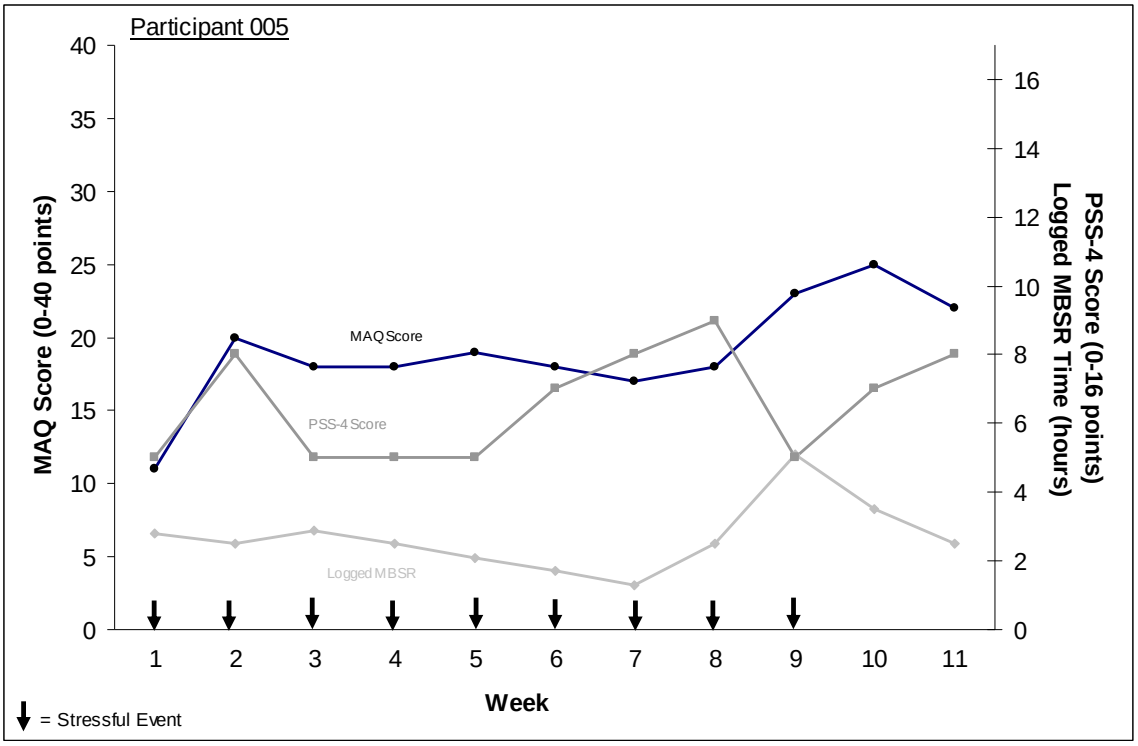


MAQ: higher scores equal greater MBSR practice
PSS-4: lower scores equal less stress

The PSS-4 score rose sharply after week 6 of the study and then returned to approximately the level at week 1 by study end. Stressful life events occurred in all but one week of the study and seemed to have little correspondence with MBSR practice time.

Participant 005. Logged MBSR practice time for participant 005 steadily declined through study week 7, then increased abruptly to a peak at week 9, followed by returning to a level approximating week 1 by study end (see Figure 14). The MAQ score roughly paralleled logged MBSR practice time after study week 1, but with an overall increase between the beginning and end of the study.

Figure 14. Weekly logged MBSR practice time, MAQ score, and PSS-4 score for participant 005.

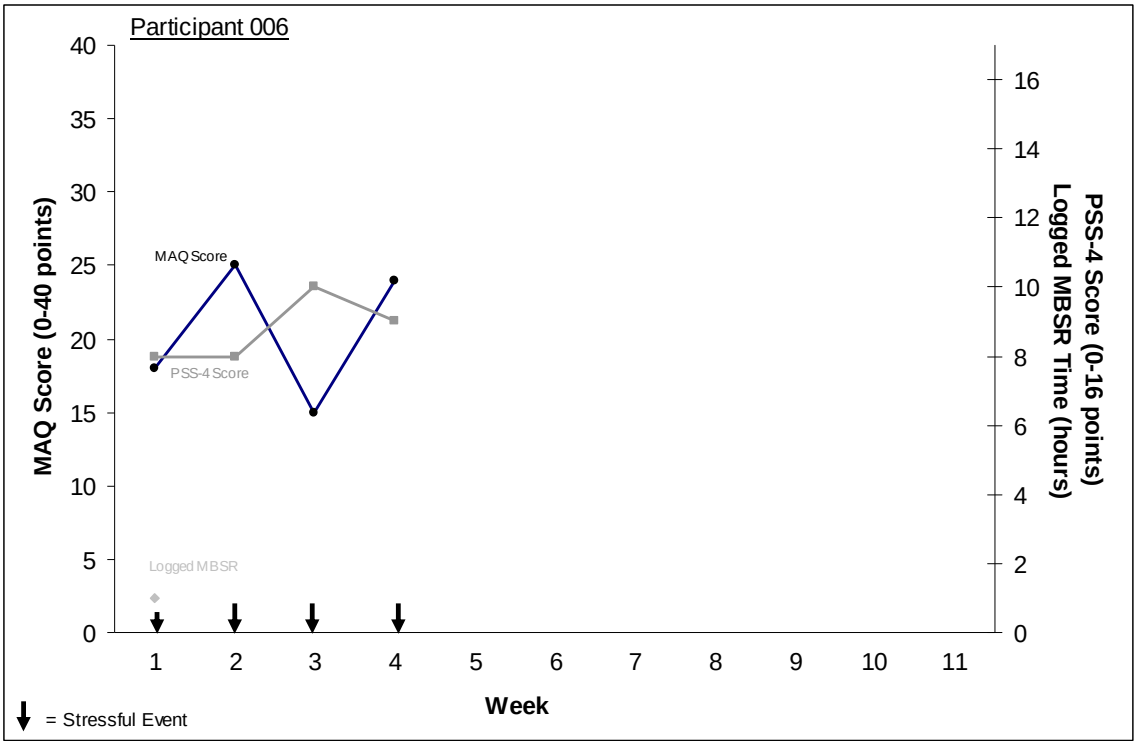


MAQ: higher scores equal greater MBSR practice
PSS-4: lower scores equal less stress

Accordingly, the PSS-4 score remained moderately elevated until study week 8 where it seemed to drop considerably as MBSR practice time increased. Stress remained low by study end, where stressful life events were no longer reported in the final two weeks. Generally speaking, stress level decreased while self-reported MBSR practice increased during the last 3 weeks of the study.

Participant 006. Only one week of logged MBSR practice time and four weeks of MAQ and PSS-4 scores were collected for participant 006 (see Figure 15). Given this short timeframe, no detectable week to week pattern was evident. This patient was withdrawn from the study following week four due to illness and hospitalization.

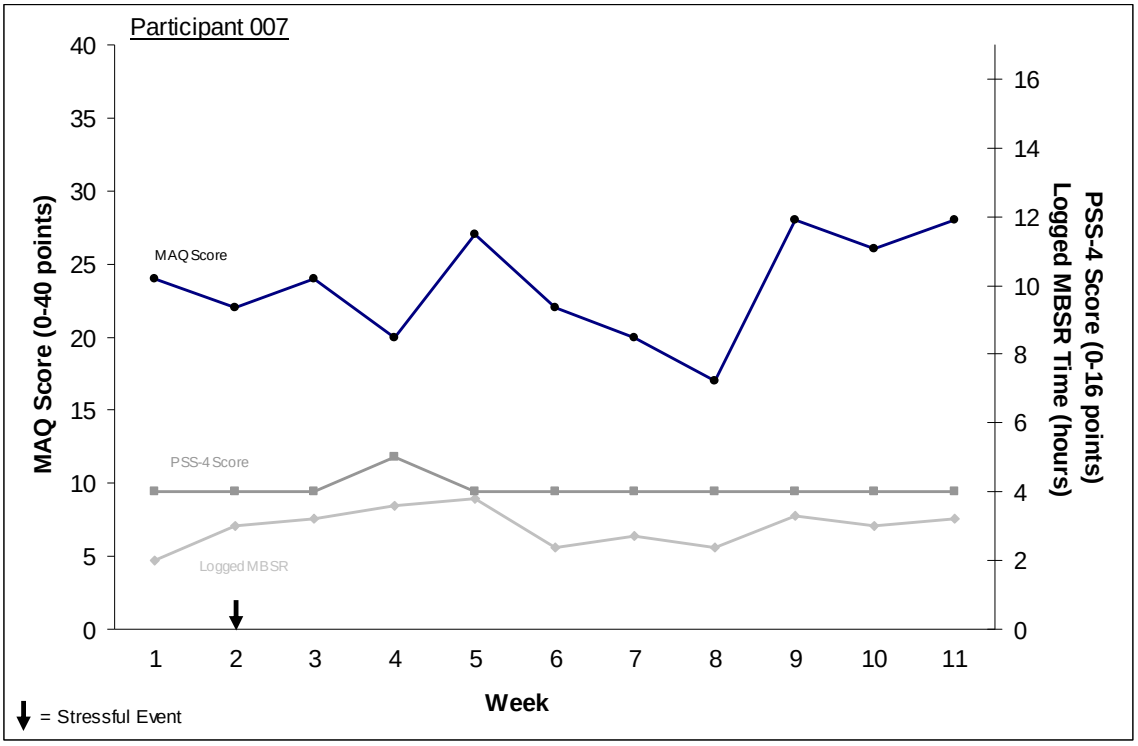
Figure 15. Weekly logged MBSR practice time, MAQ score, and PSS-4 score for participant 006.



MAQ: higher scores equal greater MBSR practice
PSS-4: lower scores equal less stress

Participant 007. Logged MBSR practice time for participant 007 increased modestly throughout the 11-week study. (see Figure 16). The MAQ score had two peaks at study weeks 5 and 9, remaining high at study completion. The pattern of logged MBSR practice seemed to roughly parallel the MAQ score over the 11-week study, but the MAQ score variables were more variable from week to week.

Figure 16. Weekly logged MBSR practice time, MAQ score, and PSS-4 score for participant 007.



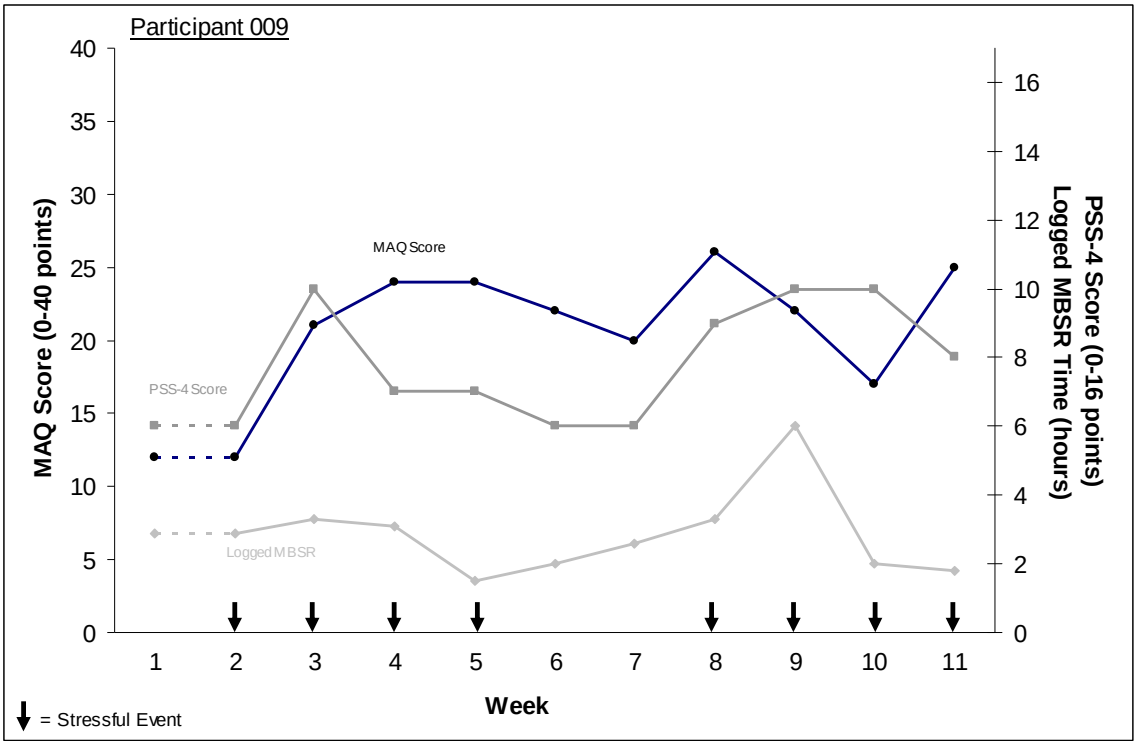
MAQ: higher scores equal greater MBSR practice
PSS-4: lower scores equal less stress

The PSS-4 score remained remarkably consistent throughout the study and seemed uninfluenced by stressful life events, which were only reported during study week 2.

Participant 008. This individual withdrew from the SMILE study after enrollment and immediately following the first MBSR classroom session.

Participant 009. Logged MBSR practice time for participant 009 was relatively stable, with a sharp peak at study week 9, followed by a sharp decline in the final two weeks of the study. The MAQ score increased rapidly during the first four weeks of the study and remained high by study end.

Figure 17. Weekly logged MBSR practice time, MAQ score, and PSS-4 score for participant 009.



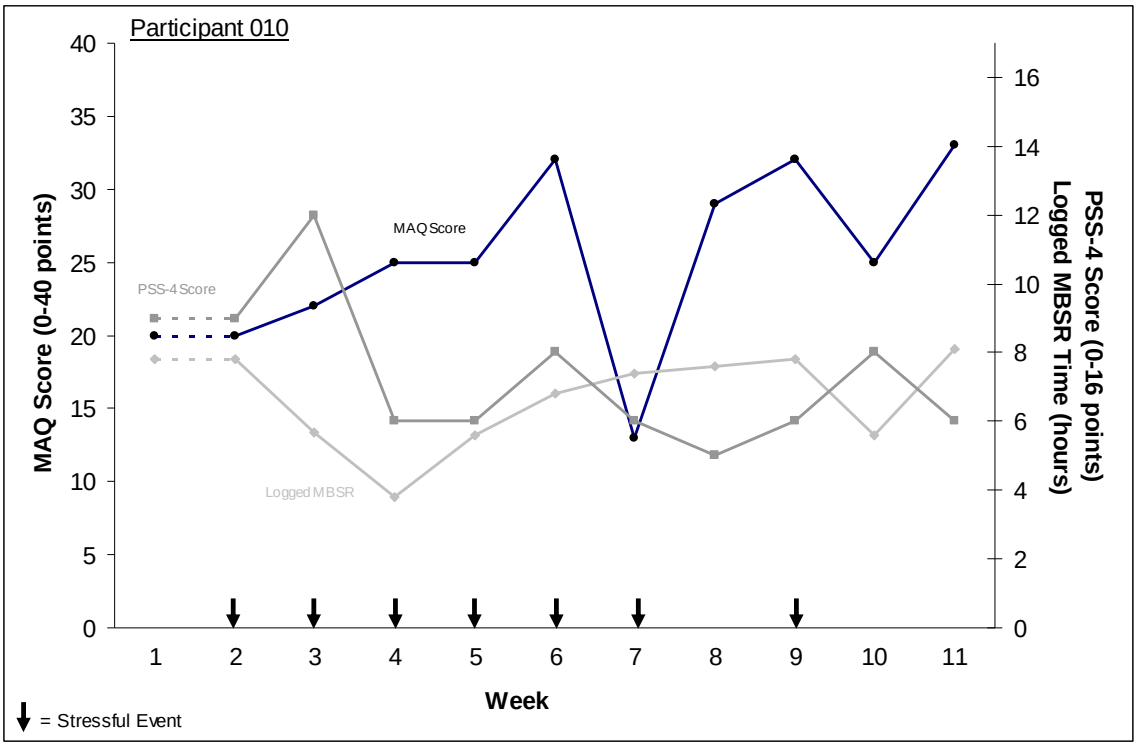
MAQ: higher scores equal greater MBSR practice
PSS-4: lower scores equal less stress

The PSS-4 scores peaked during study weeks 3 and 9, ending relatively high. This pattern of stress peaks seemed to follow reported stressful life events at (and around) the same time points. Generally speaking, stress level slightly increased and self-reported MBSR practice time slightly increased over the 11 weeks of the study. Note that the dotted line between study weeks 1 and 2 indicates that the participant joined the study during

calendar week 2 and therefore had their week 1 values imputed as the same (as described above in the Analysis section).

Participant 010. Generally participant 010 had the highest level of logged MBSR practice time in the sample (see Figure 18). Their logged hours declined for the first four weeks of the study and then steadily increased and remained high by study end. The MAQ score steadily increased throughout the study, with the exception of a sharp decline at week 7.

Figure 18. Weekly logged MBSR practice time, MAQ score, and PSS-4 score for participant 010.



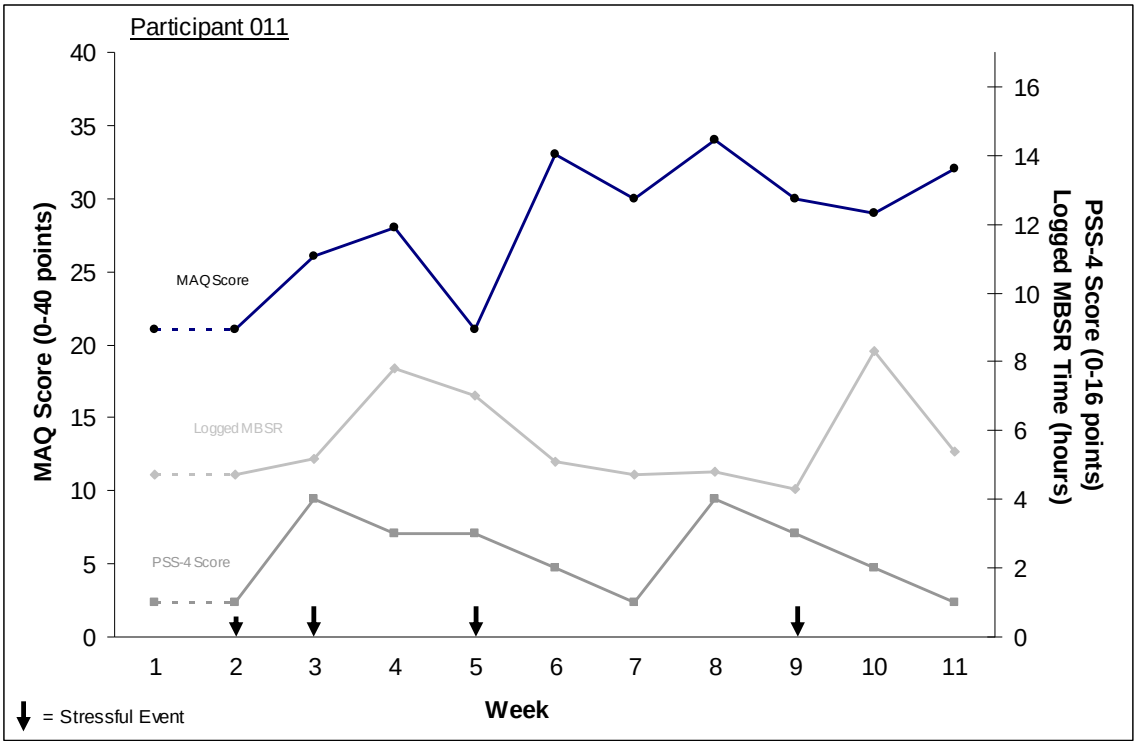
MAQ: higher scores equal greater MBSR practice
PSS-4: lower scores equal less stress

The PSS-4 score dropped sharply up until study week 4, but then remained relatively stable until study end. This pattern of stress was inconsistent with the participant's

reported stressful life events, which were nearly every week until the final two weeks of the study. Generally speaking, stress level decreased and self-reported MBSR practice time increased during the 11 week study. Note that the dotted line between study weeks 1 and 2 indicates that the participant joined the study during calendar week 2 and therefore had their week 1 values imputed as the same (as described above in the Analysis section).

Participant 011. Logged MBSR practice time for participant 011 was relatively stable throughout the study, with the exception of two peaks during study weeks 4 and 10. The MAQ score increased steadily during the entire study, with the exception of a decline during week 5, where a stressful life event also occurred.

Figure 19. Weekly logged MBSR practice time, MAQ score, and PSS-4 score for participant 011.

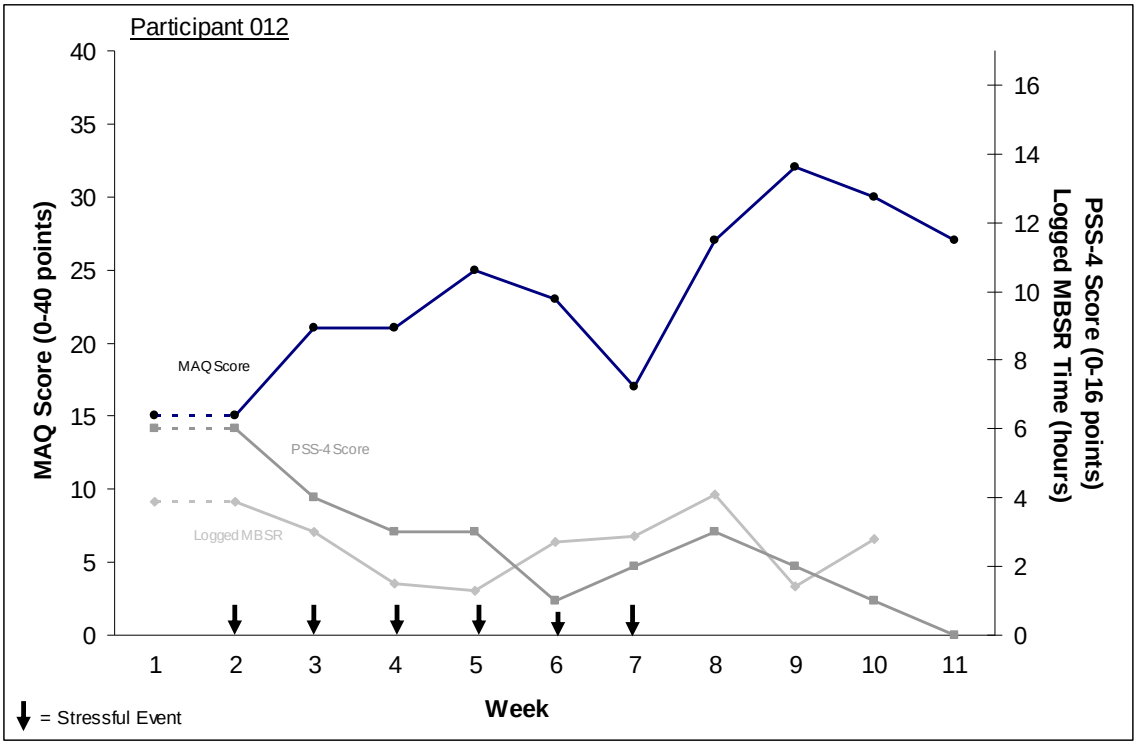


MAQ: higher scores equal greater MBSR practice
PSS-4: lower scores equal less stress

The PSS-4 score essentially ended where it started, but peaked during study weeks 3 and 8, with both peaks followed by steady declines. This pattern of stress did not seem to correspond with the participant's reported stressful life events. Generally speaking, stress scores remained stably low, while self-reported MBSR practice time increased during the 11 week study. Note that the dotted line between study weeks 1 and 2 indicates that the participant joined the study during calendar week 2 and therefore had their week 1 values imputed as the same (as described above in the Analysis section).

Participant 012. Logged MBSR practice time for participant 012 declined until study week 6, and was followed by a rapid increase until falling again at study week 9. With the exception of study week 7, the MAQ score steadily increased throughout the study. The pattern of logged MBSR practice time seemed to precisely mirror that of the MAQ score during the entire study.

Figure 20. Weekly logged MBSR practice time, MAQ score, and PSS-4 score for participant 012.



MAQ: higher scores equal greater MBSR practice
PSS-4: lower scores equal less stress

The PSS-4 score consistently declined until study completion, which was inconsistent with the participant's regularly reported stressful life events during the early to middle portion of the study. Generally speaking, stress level markedly decreased while self-reported MBSR practice time increased during the 11 week study. Note that the dotted line between study weeks 1 and 2 indicates that the participant joined the study during calendar week 2 and therefore had their week 1 values imputed as the same (as described above in the Analysis section).

Aim 4

The research question for Aim 4 was *"What are the common themes from MBSR practice experiences that influenced adherence to the program teachings?"* The results from the weekly semi-structured qualitative interviews (conducted with all participants on each of the 11 weeks) and responses from each of the five questions are presented in separate groups in order to fully outline the common themes and shared meanings. The purpose of the interviews was to identify common qualitative themes of MBSR practice experiences, including stressful life events, barriers and benefits to practice, preferences, and application of mindfulness skills that influenced adherence to the program teachings. The overarching themes identified are outlined in Table 4.

Table 4. Qualitative overarching themes from SMILE study participants.

Themes	Descriptors
Stressful Life Events	
Personal Stress	Personal and/or family health issues
Personal Health	Physical and emotional health, school, work
Family Stress	Caring for others, family obligations
Work Stress	Increasing responsibility, new technologies, job loss
MBSR Practice Challenges	
Stress	Feeling overwhelmed with life, difficulty or ineffective coping
Limited Space/Time	Organizing/prioritizing time, travel, interruptions
Lack of Routine	Difficult to plan, unpredictable schedule, no routine
Physical Limitations	Lack of energy, physical limitations, pain
MBSR Practice Benefits	
Behavioral	Self-discipline, self expression, less reactive, regular MBSR
Physical	Energy, less tense, pain relief, improved sleep, more flexible
Emotional	Personal forgiveness, acceptance, tolerance, optimism
MBSR Skill Application	
Daily Annoyances	Traffic, co-workers, household chores, waiting in line
Health	Clinic appointments, physical illness, work/family interactions

Stressful Life Events

Participants were asked about recent events in their lives that were perceived as stressful in order to determine the degree to which such events may have influenced their

adherence to MBSR practice. Both negative and positive events can lead to feelings of stress. Personal stress and work stress were identified as the two central themes that emerged in response to the question, *"Have you recently experienced a stressful life event (i.e., illness, loss of a job, death of a loved one, marriage, birth)?"* Personal health and family stress were identified as two subcategories that further described the personal stress theme.

Personal stress. Many participants identified ongoing health issues for themselves or loved ones as major underlying stressors affecting their MBSR practice time. In addition, participants discussed the impact of chronic familial and social relationship conflicts that negatively affected their role expectations within their family and/or social network structure.

Personal health. Personal health was expressed as having both a physical and emotional impact on their overall health. The following properties were described by participants to further illustrate physical components this sub-dimension: participating in a sleep study, having to use a continuous positive airway pressure device, recovering from an ankle injury, ongoing pain (i.e., hip, back, chest), hospitalizations, surgery, ER visits, having chronic illnesses (i.e., congestive heart failure, atrial fibrillation, anemia requiring blood transfusions), and loss of pregnancy. Recognizing that emotional stress typically accompanies physical stressors, participants also mentioned the following: school pressures (i.e., application process, taking GRE, coursework, pending assignments) and residential concerns (i.e., selling/buying home, moving to new apartment). An example given by one participant was "I had to go to the emergency room

for my back this last week. My back was hurting me so badly. Now it is slowly getting better, but it still hurts."

Family stress. Family stress that affected MBSR practice was commonly described through relationships and interactions among family members, role expectations, and caring for loved ones. Attributes that participants reported to support this sub-dimension include: family obligations (i.e., family reunions, birthday parties, family social events, watching grandchildren), caring for others (spousal unemployment, spousal illnesses, caring for an injured pet, friend's deaths, friend's illnesses), and strained relationships (i.e., disagreements with spouse, adults, children, and grandchildren). One participant gave this response, "I saw my son this week and we had disagreement that I would rather not discuss. I will say this though; there has been ongoing friction in our relationship. It is not something new, just something that pops up occasionally."

Work stress. Participants also identified ongoing issues at work or their spouse's work as a source of stress. Characteristics of work stress included: personal job loss, spousal job loss, searching for a job, starting own business, financial concerns, travel for work, increasing responsibilities at work, managing others, firing staff, difficulty in learning new technologies (i.e., working with computer), and lack of understanding from peers and supervisors. These work factors affected their ability to practice MBSR on a regular basis. A participant response that underscored this theme was, "It takes me 45 minutes to get to work and with the weather being so bad, I have to leave early. Sometimes the roads and traffic are bad and you can't get there as fast as you need to, but

if I am even a minute late, there is disciplinary action. This is really stressful for me on my way to work. I always worry that I am going to be late, no mater how early I leave."

MBSR Practice Challenges

Participants were asked about their barriers to regular MBSR practice in order to gauge the competing demands for this behavior that may or may not have been adequately addressed by the adherence enhancement intervention. Four significant themes emerged from the question, *"What are the top 2 or 3 challenges have you experienced in the last few weeks that have prevented you from practicing MBSR?"* These four themes included stress, limited space and time, lack of routine, and physical limitations.

Stress. The predominant theme of MBSR practice barriers that was identified by participants was stress. Examples that characterize this theme included: new stressor, difficulty coping, feeling " overwhelmed with life," unable to process new information, "my mind feels so full," high self-expectations of MBSR practice time goals, underlying chronic stress (i.e., poor health of self/spouse/friends, job loss for self/spouse and related financial concerns), trouble with technology (e.g., unable to fix compact disc player), feeling sick of practicing, not wanting to do least liked techniques, and feeling stressed about not liking some MBSR techniques. One participant expressed, "I am just too stressed out. When I am in a good mood it feels easier to practice. It is easier to do. When I feel stressed, it feels like just another thing to do. When I get stressed out, I feel like nothing can help me."

Limited space and time. The most commonly referred to barrier to regular MBSR practice was participants' limited space and time for their practice. Reasons offered by

participants that further describe this barrier included: travel for work and pleasure, always around others, not able to get away to practice, no space of one's own, distractions, interruptions when practicing, not having personal time, time for self is "sacred," family not understanding of needed alone time, role expectations, busy "doing things for others" (i.e., family, friends, social/family obligations), working long hours, keeping up with daily tasks (i.e., running errands, housework), and competing time commitments (i.e., only wanting to practice if for the full time or not at all, limited time to practice). An example given by one participant was, "Finding time is always a challenge. With all my family obligations, it is hard to set aside time for myself. Then I get upset with my husband for not giving me enough alone time. He doesn't understand that I need to do this for me."

Lack of routine. Another theme central to the concept of barriers to MBSR practice was that participants had not built MBSR into their daily routine. Responses that supported this category included: difficulty organizing time, not making mindfulness practice a priority, trying to find a way to fit MBSR practice into one's daily schedule, feeling disorganized, unpredictable daily schedule, feeling "scattered," and difficulty making MBSR part of a regular routine. One participant stated, "My hours at work are so impossible. I work all hours and it is never ending. I never know what my schedule will be from week to week, so it is making it really hard for me to get into any kind of routine."

Physical limitations. Physical limitations also served as significant barriers to regular MBSR practice and were described by participants in the following terms: having no energy, fatigue, tired, exhaustion, frequent clinical appointments, and physical

restrictions related to acute and chronic illnesses, nausea, and pain (e.g., head, neck, chest, back). One participant responded, “My schedule continues to be a challenge and I’m not feeling as well as I was. I’m really physically exhausted lately and that has made it difficult for me to practice.”

MBSR Practice Benefits

The benefits from MBSR practice have been previously identified in the literature, but asking participants, “*What are some benefits or rewards from MBSR practice that you have experienced in the last few weeks?”* provided more detailed insights into what reinforces regular MBSR practice. The responses to this question generated three key themes, including benefits related to behavior, physical body, and emotional wellbeing.

Behavioral. Outward changes made by participants that were related to the benefits they experienced included: feeling more self-disciplined, starting to slow down, assertively able to voice opinion more often, feeling more comfortable with self-expression, being less reactive, starting to journal, and having MBSR become a regular part of one’s routine. An example mentioned by one participant was, “I have an overall sense of calmness. I feel as if I have developed a sense of personal discipline, if that makes sense. What I mean is, I have been keeping on track, getting the things done that I want to get done and mindfulness has helped me focus.”

Physical. Physical changes that benefited participants were: reporting that they felt less tense, muscles were able to relax, became more flexible and limber, improved ability to sleep, pain relief, more energy, less stressed, and felt overall improved health. One participant reported, “After practicing I feel really relaxed and refreshed, like

nothing is left on my shoulders. I feel so tight when I am not practicing. I call it my inner crowding. And as I practice, this slowly melts away." Another participant said, "I have really started to examine my relationship with pain. I found that if I tell myself that I am not afraid of pain, I don't have as much. And when I do have pain, the pain doesn't last as long. I stay aware of my breathing and that really seems to help."

Emotional. Inner changes as discussed by participants demonstrated the positive benefits MBSR practice had on their mental health. These attributes included: having a sense of calmness, centering/grounding oneself, personal forgiveness, more acceptance of oneself and others, a change in perspective, feeling okay about things that cannot be controlled, strengthened faith that "things will work out," optimism, fresh perspective on old challenges, heightened awareness, appreciative, peace, presence in conversations, tolerance, less judgmental, expectations more realistic, insight of self through vivid dreams, and "enjoying the moment for what it is." One participant provided the following example, "I'm staying calmer and not letting as many things rattle me. I'm trying to be more aware of what's going on around me and what people's reactions are. This has been a really good change for me."

Application of Mindfulness Skills

Participants were asked, *"How often do you apply a mindfulness skill in response to a stressful situation? Could you provide an example?"* in order to gauge how practical the MBSR techniques were to utilize when they are arguably needed most. Many participants had difficulty responding to this question as asked because they jumped to describing how they applied their MBSR skills without answering the frequency component of the question.

Daily annoyances. The most common example given by participants was the use of a mindfulness skill during relatively minor, daily stressful encounters. These included driving in traffic, car accidents, forgetting cell phone, being late for work, difficulty with email attachments, difficulties with co-workers, encounters with strangers, household chores, financial discussions (i.e., money), and waiting in line. An example given by one participant was, "I used mindfulness in traffic the other day. I was in stop-and-go traffic for about 30 minutes on my way to work. There was nothing I could do. So instead of worrying about being late, I just drove, I actually enjoyed my time in the car. I listened to the radio and enjoyed really enjoyed this time for just me."

Health. Other examples participants gave to demonstrate the use of their mindfulness skills outside of the classroom included: during clinic appointments, in waiting rooms, dealing with physical illness, when experiencing nausea/pain, trying to fall asleep, in times of tension, when feeling impatient, need to calm down, work situations, firing employees, and during family conflicts. A response made by a participant was, "I have to prep for medical appointments and when I'm running late and rushing, it makes me really tense. I've tried to focus on my breath and it helps me slow down."

Preferred MBSR technique

A different approach was used, since a descriptive qualitative analysis was not possible for the question, *"Which MBSR techniques do you like most?"* Counting is integral to pattern recognition in qualitative analyses and aids to provide a quantitative translation of qualitative themes (Sandelowski, 2001). As outlined in Table 5, the total frequency of responses indicated the most preferred mindfulness techniques reported

cumulatively across all 11 weeks of the study. Yoga and sitting meditation were cited most frequently, whereas the body scan was also reasonably popular in the beginning sessions of the MBSR program. All other techniques were considerably less preferred. Guided meditation, either sitting or lying, using a structured CD, lying meditation, mindful walking and eating, and the overarching technique of focusing on breathing were comparably listed as infrequently preferred techniques. Of note, expressing loving kindness was not taught until very late in the program.

Table 5. SMILE Study Participant frequency counts of preferred MBSR techniques.

MBSR Technique	N=135 (responses)
Yoga	44 (33%)
Sitting Meditation	39 (29%)
Body Scan	22 (16%)
Guided Meditation	7 (5%)
Lying Meditation	6 (4%)
Mindful Walking	6 (4%)
Mindful Eating	5 (4%)
Focus on Breath	5 (4%)
Loving Kindness	1 (0%)

Frequency count (% of all responses).

Chapter 5: Discussion

This chapter summarizes the research findings and research/practice implications of the SMILE study. Specifically, changes over time in the dependent measures are discussed, along with a comparison to other relevant literature. Methodological strengths and limitations of the SMILE study are reviewed in order to make recommendations for future research. In addition, implications for future MBSR program designs as they are related to maximizing MBSR practice time are discussed.

Adherence to MBSR Practice

Adherence to the recommended level of MBSR practice showed a general trend toward increasing during the course of the 11-week SMILE study. MBSR practice time was measured in two different ways: (1) with a daily tracking log where participants self recorded their time engaged in MBSR practice, and (2) with a weekly survey where participants self-reported their frequency of MBSR techniques over the previous week (i.e., MAQ score). Among participants with both week 1 and week 11 data, logged MBSR practice time (non-significantly) increased by an estimated average of 35 minutes per week, or 15% relative to week 1 (i.e., after the first class). In addition, participants with both week 1 and week 11 data demonstrated a statistically significant 9 point (49%) increase in their average MAQ score. The MAQ score gives an arbitrary number that does not correspond to any precise unit of MBSR practice time, but higher scores indicate more frequent MBSR practice relative to lower score. The results for both logged MBSR practice time and MAQ score among program completers were consistent with those observed across the full sample, suggesting minimal attrition bias. Body scan, sitting meditation, and Hatha yoga were clearly the MBSR activities most engaged in.

This is the first known study to characterize the pattern of change over time in MBSR practice during an MBSR program. By the last week of the study, the eight participants who had data available engaged in approximately 39 minutes per day of MBSR practice according to the daily log books. The average across all weeks of the SMILE study was 35 minutes per day. This is slightly higher than the average amount of daily MBSR practice time (30 minutes per day) observed in a recent systematic review of this topic that collated evidence from multiple MBSR studies (VanWormer, & Lindquist, 2010). However, caution should be noted in comparing the results of the SMILE study to the general literature on adherence to MBSR practice. This is because very few studies in the MBSR literature report the amount of non-classroom practice time and some studies have embedded basic adherence enhancements to the standard MBSR program (typically a journal or tracking log). As such, the current estimate of average daily MBSR practice time in a standard program may be subject to non-reporting bias in the published literature. In other words, too few studies report detailed MBSR practice time that occurs outside of the classroom sessions to make a generalized estimate of how much practice time is "typical" in a given MBSR program.

Results from the MAQ score showed a significant increase in MBSR practice frequency over time, but captured a slightly different recollection of MBSR practice time. Participants were asked to self-report their general frequency of MBSR practices over the previous week. No precise indication of duration of MBSR practice is included in this measure. As such, the MAQ score provides an arbitrary point estimate of MBSR practice time. The fact that the increase in MAQ score was statistically significant, but the increase in the logged MBSR practice time may indicate that participants engaged in

some form of MBSR practice in more days per week over time, but that their duration of practice time per day remained stable or increased at a much lower rate than frequency. Other explanations may be that weekly self-reported MBSR practice frequency was more subject to optimistic recall bias relative to logged MBSR practice time. Furthermore, a real increase in logged MBSR practice time may appear diluted over time if participants forget or fail to record their practice time on some days during the later weeks of the study.

Intervention Exposure and Attendance

Participants who completed the program attended almost all of the available study sessions. The two participants that were withdrawn from the study did so during week 1 and week 5. In addition, 82% of all self-monitoring logs were submitted and 82% of all available weekly telephonic coaching calls were completed. As such, exposure to the MBSR program and most of the adherence enhancements were considered quite high and session attendance was as good as or better than what is typically reported in the MBSR literature (VanWormer, & Lindquist, 2010). Of note, session attendance was much better during the MBSR classroom sessions relative to the Cardiac Support Group sessions. This was likely due to the fact that the Cardiac Support Group sessions were much less relevant to SMILE study participants who did not have known cardiovascular disease. Participants were eligible for a total of 11 gift card incentive drawings. However, the average participant took part in only about half of total number of incentive raffle drawings available. This was because, in a given week (particularly later in the study), many participants would turn in multiple log books from previous weeks. Since a

participant was required to turn in the log book for the current week in order to be eligible for the raffle, many "missed" their weekly opportunities.

Commitment and Confidence

The increase in MBSR practice time was not paralleled by an increase in commitment or confidence for regular MBSR practice. This may have been due to the fact that neither commitment or confidence were strong cognitive mediators of MBSR practice or were imprecisely captured by the single item survey questions used in the SMILE study that were insensitive to small changes. SCT purports that some aspects of the SMILE study adherence enhancements (e.g., self-monitoring logs, telephonic coaching) would have increased commitment and confidence for regular MBSR practice. It may have been that increases in MBSR practice time were primarily driven by external reinforcers such as social praise from other participants during classroom sessions.

Stress

Perceived stress level remained stable between week 1 and week 11 of the SMILE study. This is largely inconsistent, though not unheard of, in the MBSR literature (Bishop, 2002). Although there were some indications of reduced stress at approximately the mid-point of the study, stress levels were highly variable during all weeks. There are several potential explanations for these findings. With the possible exception of participant 011, a floor effect, whereby stress level was very low to begin with, did not seem to explain the limited impact of the intervention program in regard to stress reduction. Data collection for stress began during week 1 of the SMILE study, therefore a true baseline stress level before the study initiation was unknown. It may have been that the stress reducing benefits of MBSR accrue immediately following the first MBSR

session and were not detectable with the SMILE study research design. Also, the short, 4-item version of the PSS may be less sensitive to change or more prone to statistical error as compared to longer versions of the PSS or more objective physiological stress metrics.

MBSR Adherence and Stress Change

Results from the correlation analyses generally seemed to indicate that more MBSR practice time was associated with reduced stress level. Similar to the primary analyses in Aim 1, logged MBSR practice time was non-significantly associated with stress reduction. However, the strength of the correlation between logged MBSR practice time and reduced stress in the SMILE study was nearly 50% higher than that observed from a similar analysis by Carmody and Baer (2008) (.42 versus .29). The MAQ score (during study week 11) was significantly associated with reduced stress. Specifically, each additional MAQ score point at week 11 predicted an additional 0.69 point reduction in PSS-4 score. As previously discussed, it is not clear what a 1-point increment in MAQ score equates to in terms of actual MBSR practice time, but generally speaking, practicing MBSR on more days per week seems to lead to less stress over time. At the very least, the MAQ tool seemed to be easy to administer over the phone and was sensitive to self-reported changes in MBSR practice time.

Results from the individual participants' plots of MBSR practice time and stress level by each study week support the conclusions outlined above, but display more of the intra-individual variability in these metrics over time. This is particularly useful in identifying and understanding cases that contrast sharply with the group level analytical conclusions. For example, participant 003 had a sharp increase in stress level during the final two weeks of the study. This stress increase seemed to be primarily driven by

stressful life events, not adherence to MBSR practice (which steadily increased over time). This assumption was supported by qualitative records that indicated that the participant was actively coping with a major family crisis that ultimately involved the hospitalization of an immediate family member. Similarly, participant 009 experienced an unexpected stress increase at week 8 of the study, despite a consistently established routine of MBSR practice by that time. This participant experienced a series of family and personal stressors that included the death of two family members along with temporarily debilitating medical complications. Over the 11-week study, participant 012 had steadily declining logged MBSR practice time, but steadily increasing MAQ scores. It was not clear from this participant's reported stressful life events or their qualitative records what may have explained this discrepancy. Since this participant's stress level was steadily declining during the last month of the study, it may have been that they no longer saw the benefit of recording their MBSR practice time.

Related to the individual participant plots and informed by the qualitative, semi-structured interviews, the indication of stressful life events in general did not always "map" well to an increase in stress. In some cases, it seemed as though it was the anticipation of a stressful event, rather than the precise timeframe of the event itself, that people reported as stressful. The actual resulting experiences in the ensuing weeks did not always meet their expectations in that sometimes participants were able to easily cope with stressful life events once they occurred and were intensely focused on. Of note, however, the severity of a given stressful life event was not measured in the SMILE study, only participants' overall stress level by way of the PSS-4. It may be helpful in future research to quantify the severity of stressful life events. It may also be helpful to

get a sense from a parallel control group or other historical comparison group if the number or severity of stressful events is unusually high in the group receiving MBSR.

MBSR Practice Challenges and Benefits

The qualitative semi-structured interviews indicated that lack of routine, lack of time, and limited personal space were the most common barriers to regular MBSR practice. MBSR programs essentially prescribe a home routine of MBSR techniques to be practiced for a specific frequency and duration each week. Although participants generally agreed and accepted this "assignment," they often found themselves feeling disorganized or unable to consistently plan/schedule around other life activities to fit in regular MBSR practice. Comments indicating their inability or unwillingness to prioritize MBSR practice above and beyond other responsibilities were common. Participants also found it difficult to practice MBSR in unfamiliar environments (i.e., away from home). For example, travel plans, work schedules, and inter-personal interruptions often interfered with participants being able to set aside an adequate block of time to complete their MBSR practice routine.

In terms of benefits that reinforced regular MBSR practice, it was clear from the qualitative semi-structured interviews that participants experienced major emotional growth in regard to accepting one's current state of affairs. In other words, instead of chronically ruminating, obsessing, or physically reacting to daily stressors, participants quickly learned how to reframe their thoughts and attention on present, more calming stimuli such as focusing on their breathing. An increased tolerance and forgiveness of others, as well as a more optimistic outlook, was commonly reported.

The qualitative semi-structured interviews also highlighted the complex inter-play between MBSR practice and stress levels during the study. It is rarely discussed in MBSR or other stress management programs in the scientific literature, but stress was not merely an outcome in the MBSR program in this study. For some participants, stress also appeared to have a reverse causal role on MBSR practice time. Several participants mentioned their high stress level as a reason why they did not engage in MBSR practice, even though they acknowledged that regular MBSR practice helped to relieve their stress. Some participants felt uncomfortably obligated to practice certain MBSR techniques that they did not care for. As such, it is not clear if stress is a cause or a consequence of regular MBSR practice, at least for some individuals. This underscores the need to measure both MBSR practice and stress level frequently over time in future intervention studies.

Strengths and Limitations

Perhaps the greatest strength of the SMILE study is that it is the first study to take a detailed, longitudinal examination of adherence to MBSR practice in the context of an intervention program specifically designed to maximize adherence with "best practice" techniques commonly used in other behavior change programs (Chapman, 2004). The SMILE study was a pilot study that can inform the methodological design, benchmarks, and expectations of changes (for sample size calculations) that may be observed in a larger trial. Over 83% of the sample was maintained through study week 11, indicating a program completion rate nearly identical to that observed in a systematic literature review on this topic (VanWormer, & Lindquist, 2010). The pattern of decay in MBSR practice time, as well as how it parallels with stress reductions, is displayed in detail at weekly

intervals. All data collection procedures were integrated into the existing intervention framework of weekly telephonic coaching calls, outlining a feasible model for future research in this area.

In regard to limitations, it is particularly important to acknowledge the small sample size of 12 enrollees and the lack of a no-treatment control group. The small sample only permitted estimates of change and associations. Because the SMILE study was a single-group longitudinal design, participants essentially served as their own controls. The impact of the adherence enhancement intervention on MBSR practice time above and beyond a no-treatment (or standard care) control group was not available to examine, thus the associations observed in the SMILE study must essentially be treated as hypothesis generating until a larger randomized-controlled trial can be conducted. Also, because the adherence enhancements were bundled in a package, the impact and contribution of each separate component could not be estimated. Finally, the sample was somewhat homogenous in that it was limited to females and skewed toward educated adults. Thus it remains unclear the degree to which results observed in this study would apply to those in broader segments of the population, such as males, those having low socioeconomic resources, less educated, or more ethnically diverse samples.

In regard to measurement issues, all dependent variables were self-reported during telephonic interviews with the study's principal investigator and were therefore subject to recall bias and/or demand characteristics. In addition, a true baseline was not collected since all dependent variables were initially collected during week 1 of the study (i.e., after the first MBSR session). This may severely dilute a given effect estimate reported in the SMILE study, particularly if the change/benefit for that dependent

variable occurred rapidly after enrollment. However, it was not possible to collect most of the dependent measures prior to the first MBSR session because they required at least some experience with MBSR practice before they could be accurately reported by participants. In other words, the intervention needed to be initiated before such data points could be reliably collected.

From an analytical perspective, statistically analyzing the before and after change scores (i.e., change between study week 1 and study week 11) for MBSR practice, stress, and commitment and confidence was practical and easy to interpret. However, this approach presents some loss of data. The week by week trends were disclosed to address this limited statistical analysis, but were only done so descriptively. Future research with a higher powered sample should statistically analyze various time trends in these variables.

Practice Implications

Although the methodological design of the SMILE study did not permit definitive conclusions on whether or not self-monitoring of MBSR practice adds value beyond a standard MBSR program, it seems reasonable to have some level of accountability for home based MBSR practice time in any given MBSR program. For example, instructing participants to track their MBSR practice minutes in log books, reviewing progress and providing feedback to participants could be fit into instructors' work flow. Comments made during the qualitative interviews highlighted that participants really looked forward to the weekly phone calls and were appreciative of the timely feedback. To reduce the respondent burden of daily tracking of MBSR practice time (which was less than optimal during any given week of the study), future program designers may choose to integrate

other aspects of technology beyond paper logs to make the task easier. For example, an internet log book option or Smart Phone logging of MBSR practice could be connected directly to the MBSR instructor so that they could respond more immediately to lapses in self-monitoring. If self-recording of MBSR practice time could be more complete (i.e., more log books turned in each week by each participant), it would also help improve the validity of using logged MBSR practice time as a program outcome measure. Alternative options of self-monitoring MBSR practice time were not provided in the SMILE study, but may be useful in future programs. The opportunity for financial incentives in the weekly gift card drawings did not come up in any qualitative interviews and was not fully utilized by participants, suggesting that these incentives may not be necessary or that larger monetary incentive values will be needed to make a meaningful impact. Another option worthy of investigation might be group level incentives, whereby the entire program cohort is rewarded for meeting an agreed upon group level goal of MBSR practice time.

Recommendations for Future Research

Results from the SMILE study set the groundwork for larger trials testing MBSR adherence enhancement interventions with more rigorous methodological designs. In particular, a lager sample size and a parallel control group that does not receive the MBSR adherence enhancement intervention (but does receive the standard MBSR program) would seem to be the next logical step in research. This may permit more formal dose-response analyses that could precisely more precisely establish the relationship between MBSR practice time and stress reduction in the general population. It is important to recognize, however, that it remains challenging to test a single MBSR

adherence enhancement strategy in isolation given that there are many validated options to choose from (see Robiner [2005] for a review) and most intervention trials would employ some combination of strategies in a treatment package. However, a large sample may permit sensitivity analyses that may further refine the optimal MBSR adherence intervention package.

When it comes to MBSR program fidelity, the existing literature base in this area seems to be primarily focused on the number of MBSR sessions attended (VanWormer, & Lindquist, 2010). The SMILE study was primarily focused on total MBSR practice time and it would not have been valuable to examine if MBSR session attendance was associated with stress reduction because of the small sample with very limited variability in MBSR session attendance. If MBSR session attendance truly is a proxy for MBSR practice time or negatively correlated with stress change, however, it would make sense for future research to study MBSR session attendance as a dependent outcome measure. In other words, examine what predicts MBSR session attendance or examine how an MBSR session attendance intervention impacts the number of attended sessions. Further, it is important to investigate what the minimally effective "dose" of MBSR session attendance is. This information would be an important consideration for future program designs since the current recommendation of ≥5 of the 8 available sessions to constitute program completion (Salmon, Santorelli, Sephton, & Kabat-Zinn, 2009) does not seem to be based on evidence.

Conclusions

The SMILE study involved the use of an adherence enhancement package as part of an MBSR program where self-reported MBSR practice levels increased over 11

weeks. Secondary evaluations indicated that the MBSR practice level at study end (i.e., week 11) was correlated with stress reduction between study weeks 1 and 11. Other SMILE study outcomes, including logged MBSR practice time, commitment and confidence for regular MBSR practice, and perceived stress level did not improve between study weeks 1 and 11. Weekly semi-structured qualitative interviews provided insights during the course of the study and indicated that participants primarily found lack of time, lack of routine, and limited personal space/understanding within their social environment as barriers to regular MBSR practice. Furthermore, participants indicated emotional growth, including improved tolerance and less natural reactance to stressors, as the primary rewards of regular MBSR practice (see summary of findings in Figure 21). Curiously, although the reported stressful life events were clearly influential on both stress level and MBSR practice for most individual participants, they did not seem to correlate at all for some individuals.

Figure 21. Evidence informed conclusions from the SMILE study.

- Weekly frequency of self-reported MBSR practice, per the Mindfulness Adherence Questionnaire scores, increased by 49% over the 11-week intervention.
- Frequency of self-reported MBSR practice at study end (i.e., week 11) was correlated with stress reduction over the 11-week intervention. Specifically, 48% of the change in participants' Perceived Stress Scale scores was explained by participants' week-11 Mindfulness Adherence Questionnaire scores.
- All other SMILE study dependent variables, including logged MBSR practice, commitment and confidence for regular MBSR practice, and Perceived Stress Scale scores did not improve over the 11-week study.
- Participants indicated that lack of time, lack of routine, and limited personal space were the most common barriers to MBSR practice.
- Qualitatively, participants cited improved tolerance to and less emotional reactance to major stressors in their lives as the primary benefits of the program.

Overall, the SMILE study intervention package was feasible and acceptable to participants, as indicated by the high degree of exposure to its components, particularly the weekly submission of self-monitoring logs and completion of weekly telephonic coaching calls. It was not clear how helpful the incentive gift card drawings were. The SMILE study had several methodological limitations that limited cause-and-effect conclusions since the sample was small and did not include a parallel control group. Future research should address these research design shortcomings and use more objective measures of chronic stress (e.g., serum cortisol, immunoglobulin A). Because overall MBSR practice time was associated with reduced stress, future MBSR practice programs should consider adding more professional accountability and curriculum on the importance of adherence as it relates to the recommended level of home-based practice time of MBSR techniques.

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Footnotes

[1] The Lite Hearten pilot study was a randomized, controlled design with primary aims to improve overall cardiac functioning and blood flow efficiency in female, cardiovascular disease patients (R. Lindquist, personal communication, September 8, 2009). Participants in the Lite Hearten study were randomly assigned to one of three groups, including: (1) Stress Management Program, (2) Aerobic Exercise, or (3) Control. The stress management and exercise groups received a 12-week intervention beginning immediately after enrollment.

Appendix A. MBSR Participation and Adherence Literature Review.

REFERENCE, SAMPLE, & DESIGN	ADDITIONAL ADHERENCE STRATEGIES	OBSERVED MBSR PARTICIPATION	STRESS OUTCOMES	COMMENTS
Carlson, et al. (2005) 63 adults with cancer recruited from a clinic based MBSR waitlist in Alberta. The mean age was 54 years, 78% were women and 71% were married. Single group pre-post test	• Meditation self-monitoring log – Daily tracking of minutes spent in yoga and meditation.	63 (100%) of the participants completed 5 or more MBSR sessions.	1) Symptom of Stress Inventory (SOSI), score. Measures were assessed at baseline and 8-weeks follow-up. Compared to baseline, participants significantly reduced their total SOSI score (98.0 vs. 75.4) at follow-up.	
Carlson, et al. (2007) 59 adults with breast or prostrate cancer recruited through clinic posters/pamphlets in Alberta. The mean age was 55 years, 83% were women and 71% were married. Single group pre-post test	• Meditation self-monitoring log – Daily tracking of minutes spent in yoga and meditation.	52 (88%) of the 59 participants completed 5 or more MBSR sessions. The average total home-based meditation/yoga practice time was 37 minutes per day.	1) Symptom of Stress Inventory (SOSI), score. Measures were assessed at baseline, 8-weeks, 6-months, and 12-months follow-up. Compared to baseline, participants significantly reduced their total SOSI score (81.6 vs. 68.2) at follow-up. Scores remained low at 6-months and (66.7) and 12-months (62.6).	The stress outcomes were based on the 31 participants who were available for all 4 follow-ups.
Carmody, et al. (2008) 62 adults referred by their health care provider or self-referred to a MBSR program in Massachusetts. Demographics were reported on 44 participants who provided pre and post data. The mean age was 48 years and 75% were women.	• Mindfulness self-monitoring log – Daily tracking of minutes spent in formal (meditation) and informal (being mindful) home practice.	52 (84%) of the 62 participants completed the program. The average total home-based formal (meditation) and informal (being mindful) practice time was 38 minutes per day.	1) Global Severity Index (GSI), score. Measures were assessed at baseline and 7-weeks follow-up. Compared to baseline, participants significantly decreased their GSI score (0.9 vs. 0.5) at follow-up.	Completion of the MBSR program was not defined.

Retrospective cohort design				
Davidson, et al. (2003) 48 employed adults were recruited in a biotechnology corporation in Wisconsin. Demographics were reported on 41 participants who had complete data. The mean age was 36 years and 71% were women. Randomized-controlled trial	• Meditation self-monitoring log – Daily tracking of minutes spent in formal meditation.	41 (85%) of the 48 participants completed the program. The average total home-based formal (meditation) practice time was 41 minutes per day.	No stress outcomes were reported. Measures were assessed at baseline, 8-weeks, and 6-months follow-up.	Although 41 participants completed the program and MBSR participation at home was described, no indication of MBSR participation during sessions was reported.
Davis, et al. (2005) 18 adult smokers recruited by phone in Wisconsin. The mean age was 45 years and 56% were women. Single group pre-post test	• Meditation self-monitoring log – Daily tracking of minutes spent in formal meditation.	13 (72%) of the 18 participants completed 5 or more MBSR sessions. The average total home-based formal (meditation) practice time was 33 minutes per day.	1) Perceived Stress Scale (PSS), score. Measures were assessed at baseline and approximately 6-weeks follow-up. Outcomes were stratified by moderately (< 270 min/wk) and highly (≥ 270 min/wk) compliant meditators. Compared to moderately compliant mediators, highly compliant mediators significantly decreased their PSS score (-3.0 vs. 5.0) at follow-up.	Additional components to standard MBSR course included: weekly carbon monoxide testing and recommended quit date.
Marcus, et al. (2003) 21 adult residents of substance abuse center recruited through staff referrals in Texas. The mean age 33 years and 14% were women. Single group pre-post test	• Meditation self-monitoring log – Daily tracking of minutes spent in meditation.	18 (86%) of the 21 participants completed the program.	1) Perceived Stress Scale (PSS), score. Measures were assessed at baseline and approximately 8-weeks follow-up. No significant findings were observed.	Although 18 participants completed the program, no precise measures of MBSR participation were reported.
Beddoe, et al. (2004) 23 nursing students recruited through a	• Journal keeping – Non-directed encouragement to write about	18 (78%) of the 23 participants completed all MBSR sessions.	1) Derogatis Stress Profile (DSP), score.	The means of the stress outcome were unspecified.

Baccalaureate program in California. The mean age was 25 years and 100% were women. Single group pre-post test	feelings, adjustments, benefits, and progress regarding MBSR training.		Measures were assessed at baseline and 8-weeks follow-up. Compared to baseline, participants significantly improved their DSP score at follow-up.	
Kreitzer, et al. (2005) 20 adult solid organ recipients recruited through referrals, newspaper ads and brochures in Minnesota. The mean age was 49 years, 70% were women, and 30% were married. Single group pre-post test	• Meditation self-monitoring log – Daily tracking of minutes spent in meditation. • Phone follow-ups – Weekly the first month post program, monthly thereafter, encouraging home meditation.	19 (95%) of the 20 participants completed 5 or more MBSR sessions. The average total home-based formal (meditation) practice time was approximately 25 minutes per day.	1) State-Trait Anxiety Inventory (STAI), score. Measures were assessed at baseline, 8-weeks, 20-weeks, and 8-months follow-up. No significant findings were observed.	Analyses were adjusted for potentially confounding covariates.
Koszycki, et al. (2007) 58 adults with social anxiety disorders recruited through media advertisement in Ontario. Demographics were reported on 47 participants who completed all follow-up measures. The mean age was approximately 38 years, 53% were women and 30% were married. Randomized-controlled trial	• Meditation self-monitoring log – Daily tracking of minutes spent in meditation.	22 (85%) of the 26 participants completed 5 or more MBSR sessions.	No stress outcomes were reported. Measures were assessed at baseline and 8-weeks follow-up.	
Pradhan, et al. (2007) 63 adults with rheumatoid arthritis recruited through newspaper ads, rheumatology presentations, health fairs and community flyers in Maryland. The mean age was approximately 54 years, 87% were women and 63% were married. Randomized-controlled trial	• Meditation self-monitoring log – Daily tracking of MBSR practices.	28 (90%) of the 31 participants completed the program (the median number of sessions attended was 8). The average total home-based MBSR practice time was approximately 50 minutes per day.	1) Global Severity Index (GSI), score. Measures were assessed at baseline, 8-weeks, and 6-months follow-up. Compared to the control group, participants in the MBSR group had significantly greater improvement in their GSI score (-0.2 vs. 0.0) at 6-month follow-up.	Several refresher classes were offered after the initial 8-week program.
Sephton, et al. (2007)	• Phone follow-	42 (82%) of the 51	No stress	

91 adults with fibromyalgia recruited through television broadcasts and newspaper ads in Kentucky. The mean age was approximately 48 years, 100% were women and 60% were married. Randomized-controlled trial	ups – Reminder calls after missed sessions.	participants completed 4 or more MBSR sessions.	outcomes were reported. Measures were assessed at baseline, 8-weeks and 16-weeks follow-up.	
Shapiro, et al. (2007) 64 adult students recruited through graduate psychology courses in California. Demographics were reported on 54 participants who completed all follow-up measures. The mean age was 29 years and 90% were women. Non randomized-controlled trial	• Meditation self-monitoring log – Daily tracking of MBSR practices.	22 (100%) of the 22 participants completed the program. The mean amount of total time spent in MBSR activities was 8 minutes per day.	1) Perceived Stress Scale (PSS), score. Measures were assessed at baseline and 9-weeks follow-up. Compared to the control group, participants in the MBSR group had a significantly lower PSS score (18.4 vs. 22.3) at follow-up.	Although 22 participants completed the program, no precise measures of MBSR participation were reported.
Morone, et al. (2008) 37 adults with chronic low back pain recruited through clinic flyers in Pennsylvania. The mean age was 75 years, 57% were women, and 62% were married. Randomized-controlled trial	• Meditation self-monitoring log – Daily tracking of minutes spent in meditation.	13 (68%) of the 19 participants completed the program (average number of sessions attended was 6.7). The average total (meditation) practice time was approximately 32 minutes per day.	No stress outcomes were reported. Measures were assessed at baseline, 8-weeks, and 12-weeks follow-up.	
Shapiro, et al (2008) 47 adult students recruited through flyers and course presentations in California. Demographics were reported on 44 participants who completed all follow-up measures. The mean age was 29 years and 90% were women. Randomized-controlled trial	• Meditation self-monitoring log – Daily tracking of MBSR practices.	15 (88%) of the 17 participants completed the program.	No stress outcomes were reported. Measures were assessed at baseline, 8-weeks, and 16-weeks follow-up.	Randomization procedure was confounded by allowing some participants to voluntarily switch groups. And, although 15 participants completed the program, no precise measures of MBSR participation were reported.
Kieviet-Stijnen, et al. (2008) 93 adult cancer patients	• Cognitive log – Recording of frequent thoughts,	77 (83%) of the 93 participants completed the program.	No stress outcomes were reported.	Although 77 participants completed the post-program,

recruited from clinical practice in the Netherlands. Demographics were reported on 47 participants who completed all follow-up measures. The mean age was 48 years and 72% were women. Single group pre-post test	stressful communications, and physical sensations. • Personal training goals – Non-specific.		Measures were assessed at baseline, 8-weeks, and 1-year follow-up.	no precise measures of participation to MBSR were reported.
Vieten, et al. (2008) 34 pregnant adults with self-reported mood disturbances recruited through physician referrals and birthing class ads in California. Demographics were reported on 54 participants who completed all follow-up measures. The mean age was 34 years, 100% were women and 100% were married. Randomized-controlled trial	• Meditation self-monitoring log – Daily tracking of MBSR practices.	13 (87%) of the 15 participants completed the program (mean number of sessions was 7.2). The mean amount of total time spent in MBSR activities was 11 minutes per day.	1) Perceived Stress Scale (PSS), score. Measures were assessed at baseline, 9-weeks, and 12-weeks follow-up. No significant findings were observed.	

Appendix B. Consent Form

Consent Form

Minneapolis Heart Institute Foundation / Abbott Northwestern Hospital Stress Management, Incentives, Logging, and Enhancements (SMILE) Study

This study is being conducted by Arin VanWormer, MS, RN and Ruth Lindquist, PhD, RN from the University of Minnesota, Abbott Northwestern Hospital, and the Women's Heart Health Program of Minneapolis Heart Institute® at Abbott Northwestern Hospital. Neither the investigators nor the study staff has any financial incentives relating to your participation in this study or any other financial interests within the scope of this study.

You are invited to participate in a research study. You were selected as a possible participant in this study because you are participating in the Mindfulness-Based Stress Reduction course offered through the Lite-HEARTEN Study.

BACKGROUND AND PURPOSE

Patients participating in stress management programs sometimes have challenges following through with all of the recommended strategies for managing their stress. Research has shown that people can gain maximum benefits from these programs when they attend all of the sessions and practice the techniques regularly.

The purpose of this study is to help you find ways to use the strategies you learned during the stress management program. This will be measured using survey responses, brief interviews, and a daily practice journal.

Please read this form and ask any questions you may have before agreeing to be in the study. It is important that you read and understand the following explanation, which describes the research subjects' rights. Also below, we describe the procedures, benefits, risks, discomforts and precautions associated with this study. We also describe the alternative procedures that are available to you and your right to withdraw from the study at any time.

Research Subject's Bill of Rights:

People who volunteer to participate in an experiment (also called a research study or clinical trial) need to understand what is expected of them and why the research is being done. As you think about whether or not to volunteer, it is important that you know that you have rights in place to help protect you. These rights, listed below, will be further explained as you read this informed consent document.

If you are asked to participate in a research study, you have the right to:

- be told the purpose and details of the research study,
- have the drugs or devices (tools or pieces of equipment) used in the research study described,
- have the procedures of the research study and what is expected of you explained,
- have the risks, dangers, and discomforts of the research study described,
- have the benefits and advantages of the research study described,
- be told of other drugs, devices or procedures (and their risks and benefits) that may be helpful to you,
- be told of medical treatment available to you should you be injured because of the research study,
- have a chance to ask questions about the research study,
- quit the research study at any time without it affecting your future treatment,
- have enough time to decide whether or not to take part in this research study and to make that decision without feeling forced or required to participate, and
- be given a copy of this signed and dated informed consent form.

STUDY PROCEDURES

In addition to the stress management program you are already participating in, this study will included several enhanced components, including:

- Self-monitoring – You will be provided a daily log book to track how often you practice Mindfulness Based Stress Reduction (MBSR) techniques, such as meditation, yoga, and body scans. You will be asked to submit your log book to the program instructor each week during your normal classroom session.
- Telephonic coaching – You will be contacted each week by phone (from a study staff member) to discuss your progress on MBSR practice, set future goals, and problem solve any challenges you face. Each call is designed to last about 20 minutes with the aim to support your efforts as part of the stress management program.
- Log Book – Each week that you turn in your log book, you will be entered into a prize raffle, where the winner will receive a $20 gift card to a local retailer. One individual will be drawn from the group each week, and the raffle will occur at the end of that evening's session.

Information will be collected on MBSR practice habits, commitment and confidence for regular MBSR practice, and stress level. In addition, during one of the weekly telephonic coaching calls, each month, you will be asked a series of brief interview questions on your MBSR practice experiences to date.

RISKS AND DISCOMFORTS

The possible risks that are associated with these measures include:

1) Every effort will be made to be sure that your participation in this study and all records of your participation will remain confidential. However, confidentialy can

not be absoultely guarenteed. Due to the nature clinical trial oversight, some funding and regulatory agencies may have the right to review the records of this study. These agencies include Abbott Northwestern Hosptial and University of Minnesota Institutional Review Boards. No information that could identify you, such as names or addresses, will be used when the results of this study are published or presented.

BENEFITS

You may or may not benefit directly from participation in this study. Your participation will provide information that may in the future benefit others and will help us refine the procedures and conduct of our future studies in this area.

ALTERNATIVES

The alternative would be to not participate in this study. If you chose not to participate, you will be able to participate in the stress management program without these study components.

COSTS

There is no cost for participating in this study. Also, there is no compensation for participating in this study, but you may win one of the incentive prize drawings.

COMPENSATION FOR A RESEARCH-RELATED INJURY

If you are injured as part of your participation in this research study, treatment will be available, including first aid, emergency treatment and follow-up care, as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company.

CONFIDENTIALITY

Every reasonable effort will be made to keep your records of this study confidential. Your identity, clinic and hospital records, and other information that is obtained in this trial are confidential, except as disclosure is required by law. This information will not be revealed to any person, except personnel involved with the study at the University of Minnesota, the Minneapolis Heart Institute/Foundation, other applicable regulatory authorities, or the Abbott Northwestern Hospital Institutional Review Board, without your consent. If the results of this study are published, your identity will remain confidential.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this research study is voluntary. You can refuse to participate or you can withdraw from this study at any time for any reason. Your decision whether or not to participate will not affect your medical care.

QUESTIONS

You have the right to ask questions concerning this study at any time. If you have questions, you may contact one of the study investigators:

Arin VanWormer at 651-308-3314 or Dr. Ruth Lindquist at 612-624-5646.

You may also contact the Abbott Northwestern Hospital Institutional Review Board at 612-262-4920 for any questions about your rights as a research participant, or the University of Minnesota Institutional Review Board at 612-626-5654.

STATEMENT OF CONSENT

This research study and related procedures have been explained to me to my satisfaction. I understand that my participation in this study is voluntary and that I may withdraw my consent at any time without penalty, prejudice or loss of benefits to which I am entitled. I have been given the opportunity to ask questions and all of my questions have been answered. I will be given a signed copy of this consent form for my records.

I voluntarily agree to participate in this study.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent

Appendix C. Contact Information Form

Contact Information Form

Name: _____

Address: _____

_____

_____

Preferred Phone: _____

Alternate Phone: _____

Email: _____

Best time to call you? _____

_____

_____

Appendix D. Participant Demographic Information Form

Participant Demographic Information Form

Subject: ID# _____ Date: _____

Please fill out the following information:

1. Age _____
2. Date of Birth _____
3. Marital Status Married ____ Single ____ Divorced ____

   Widowed ____ Living with Someone _____
4. Education: Check the highest schooling you have completed (Circle one):
   - Less than 9th grade 1
   - 9th to 12th grade (no diploma) 2
   - High school graduate (or equivalency) 3
   - Some college or associate degree 4
   - Bachelor's Degree or higher 5
5. Race/Ethnic Origin (please check one)

   African American _____

   Caucasian _____

   Hispanic _____

   Asian American _____

   Multiracial/Biracial _____

   Pacific Islander or Native Hawaiian _____

   American Indian/Alaska Native _____

   Other (please specify) _____
6. What statement best describes your **employment status**? (Circle one):
   - I am working full-time for pay (over 35 hours per week) 1
   - I am working part-time for pay (less than 35 hours per week) 2
   - I am working as homemaker in my own home 3
   - I am retired 4
   - Other: 5

7. Current total annual household income (check one):

Less than $5,000 _____

$5,000 - $9,999 _____

$10,000 - $29,999 _____

$20,000 - $39,999 _____

$30,000 - $49,999 _____

$40,000 - $59,999 _____

$50,000 - $75,000 _____

More than $75,000 _____

Appendix E. Mindfulness Based Stress Reduction Log Book

MBSR Log Book Instructions:

Record all of the MBSR practice you do, outside of the time spent in the classroom. For each MBSR activity you perform each day, place a check mark in a new row and record the time you started the activity and the time you stopped the activity. In addition, rate the quality of each activity in the far right column. Quality ratings should be on a scale from 0 to 10 (with 10 being the highest quality and 0 being the lowest quality. See example below.

Date: *1-22-10*

Daily Mindfulness Based Stress Reduction (MBSR) Practice Log

	Body Scan	Sitting Meditation	Lying Meditation	Mindful Eating	Mindful Walking	Hatha Yoga	Chi-Gong	Quality Rating
		√						*7*
			√					*4*
					√			*6*
Total Time (minutes)		*45*	*15*		*30*			

Thoughts, comments, and reflections on today's MBSR practice:

I really enjoyed waking up and doing a body scan. It helped set the tone of the entire day.

Date: _____

Daily Mindfulness Based Stress Reduction (MBSR) Practice Log

	Body Scan	Sitting Meditation	Lying Meditation	Mindful Eating	Mindful Walking	Hatha Yoga	Chi-Gong	Quality Rating
Total Time (minutes)								

Thoughts, comments, and reflections on today's MBSR practice:

Source: VanWormer, A.M. (2010).

Appendix F. Mindfulness Adherence Questionnaire

Mindfulness Adherence Questionnaire (MAQ)

Directions: Please give the response that best answers each of the following eight questions.

1.	Over the past 7 days, how often have you performed a body scan?	❍ Never ❍ About once per week ❍ 2 or 3 times per week ❍ 4 or 5 times per week ❍ 6 or 7 times per week ❍ More than 7 times per week
2.	Over the past 7 days, how often have you practiced sitting or lying meditation?	❍ Never ❍ About once per week ❍ 2 or 3 times per week ❍ 4 or 5 times per week ❍ 6 or 7 times per week ❍ More than 7 times per week
3.	Over the past 7 days, how often do you feel you have "lived in the moment" or been focused on the present?	❍ Never ❍ About once per week ❍ 2 or 3 times per week ❍ 4 or 5 times per week ❍ 6 or 7 times per week ❍ More than 7 times per week
4.	Over the past 7 days, how often have you been mindful in your interactions with other people?	❍ Never ❍ About once per week ❍ 2 or 3 times per week ❍ 4 or 5 times per week ❍ 6 or 7 times per week ❍ More than 7 times per week
5.	Over the past 7 days, how often have you practiced a mindful exercise, such as yoga, mindful walking, or chi-gong?	❍ Never ❍ About once per week ❍ 2 or 3 times per week ❍ 4 or 5 times per week ❍ 6 or 7 times per week ❍ More than 7 times per week
6.	Over the past 7 days, how often have you been aware of your breathing?	❍ Never ❍ About once per week ❍ 2 or 3 times per week ❍ 4 or 5 times per week ❍ 6 or 7 times per week ❍ More than 7 times per week
7.	Over the past 7 days, how often have you been mindful during routine activities, such as walking, driving, or eating?	❍ Never ❍ About once per week ❍ 2 or 3 times per week ❍ 4 or 5 times per week ❍ 6 or 7 times per week ❍ More than 7 times per week
8.	Over the past 7 days, how often have you given yourself or others "loving kindness?"	❍ Never ❍ About once per week ❍ 2 or 3 times per week ❍ 4 or 5 times per week ❍ 6 or 7 times per week ❍ More than 7 times per week

Source: VanWormer, A.M., & Petroskas, D. (2010).

Appendix G. Commitment and Confidence Scales

Commitment and Confidence Scales:

9.	On a scale from 0 to10, with zero being not important at all and ten being most important, how important is it for you to engage in MBSR practice for at least 4.5 hours per week?	❍ 0 ❍ 1 ❍ 2 ❍ 3 ❍ 4 ❍ 5	❍ 6 ❍ 7 ❍ 8 ❍ 9 ❍ 10
10.	On a scale from 0 to10, with zero being not confident at all and ten being most confident, how confident are you that you will engage in MBSR practice for at least 4.5 hours per week?	❍ 0 ❍ 1 ❍ 2 ❍ 3 ❍ 4 ❍ 5	❍ 6 ❍ 7 ❍ 8 ❍ 9 ❍ 10

Source: VanWormer, A.M. (2010).

Appendix H. Perceived Stress Scale–4

Perceived Stress Scale–4:

11.	In the last month, how often have you felt that you were unable to control the important things in your life?	❍ Never ❍ Almost never ❍ Sometimes ❍ Fairly often ❍ Very often
12.	In the last month, how often have you felt confident about your ability to handle your personal problems?	❍ Never ❍ Almost never ❍ Sometimes ❍ Fairly often ❍ Very often
13.	In the last month, how often have you felt that things were going your way?	❍ Never ❍ Almost never ❍ Sometimes ❍ Fairly often ❍ Very often
14.	In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	❍ Never ❍ Almost never ❍ Sometimes ❍ Fairly often ❍ Very often

Source: Cohen, S., & Williamson, G. (1988).

Appendix I. Qualitative Semi-structured Interview Questions

Qualitative Semi-structured Interview Questions:

15.	Have you recently experienced a stressful life event (i.e., illness, loss of a job, death of a loved one, marriage, birth)?	
16.	What are the top 2 or 3 challenges you have experienced in the last few weeks that have prevented you from practicing MBSR?	
17.	What are some benefits or rewards from MBSR practice that you have experienced in the last few weeks?	
18.	Which MBSR techniques do you like most?	
19.	How often do you apply a mindfulness skill in response to a stressful situation? Could you provide an example?	

Source: VanWormer, A.M. (2010).

Appendix J. Women's Cardiac Support Group: Session I

Lite HEARTEN
Women's Cardiac Support Group
Session I

---

1. Welcome and Introductions

2. Overview

3. Background
    a. Women and heart disease
    b. Women's Heart Health Program of the Minneapolis Heart Institute R®
    c. Kathy Kastan
    d. Summer Pilot
    e. Women's Only Cardiac Support Group
    f. Lite-"HEARTEN"
    g. Summit

4. Lite-HEARTEN Support Group Curriculum
    a. *From the Heart: A Woman's Guide to Living Well with Heart Disease* – Kathy Kastan, LCSW, MAED
    b. Requested topics
    c. Preferred format

5. Schedule

6. Framework (from Kabat-Zin)

7. Story-Telling (Brown et al.; Struthers)
    a. What is it?
    b. Benefits
    c. Techniques
    d. Examples
    e. "Practice"
    f. Sharing

8. Written Stories –Kathy Kastan
    a. Foreword
    b. Part I: Beginning the Recovery Process

c. Part II: Rebuilding your Sense of Self
d. Part III: Negotiating the Outer World

9. Discussion

10. Close

Source: Lindquist, R., & Windenburg, D. (2010).

Appendix K. Women's Cardiac Support Group: Session II

Women's Only Cardiac Support Group
"Book Club"
Session II
Covers Section I of Kastan's *From the Heart*

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1. Welcome and Introductions

2. Overview of first section and format.

    a. Introduction – Co-moderator?

    Discussion Questions:

    Have you experienced overload with "lots on your plate?"
    What does your body tell you when you are "over-doing it?"
    How do you experience stress? How do you respond?
    Do you related to the experience of "piled up stress?"
    How can you work with providers to get the help that you need?
    Are the experiences of Kathy ones with which you can empathize?

    b. The First Steps – Co-moderator?

    Discussion Questions:

    What is your pattern of coping?
    What advice would you give a woman newly diagnosed with heart disease?
    Has your diagnosis transformed you in any way?
    How have you responded to any new demands of living with heart disease? Have you made any changes?
    Do you feel any "guilt" in taking care of yourself and your needs?
    Do you say "no?"
    In the course of your disease or recovery, did you feel lonely or isolated? How did you overcome this?
    How are you addressing your risk factors to stay healthy?
    How do you view your medications and regimen for cardiac health?

    c. Emotional Pulse – Co-moderator?

    Discussion Questions:

    Do you check your emotional pulse?
    How can you cope with mood swings?

Do you resonate with or relate to Kathy's comments on stages of grief and coping with emotions?
What "advice" did Kathy give you that resonated with you or was helpful?
Do you have any advice for others as to how to cope with fears, anxiety or sadness?
Kathy suggested that you let your feelings surface and then deal with them. Does that work for you? Do you have someone to share these deeper feelings with?

3. How do you get the support that you need? – Co-moderator?

   Discussion Questions:

   Opening line of communication.
   Consider others' perspective.
   Can using "I" vs. "you" messages be helpful?
   How is a support system or community created or obtained? How is support experienced? How do you know that you have it?
   How is support helpful?
   How can your family help?
   How can you get the support that you need when you need it?

4. Close

Source: Lindquist, R., & Windenburg, D. (2010).

Appendix L. Women's Cardiac Support Group: Session III

Women's Cardiac Support Group
"Book Club"
Session III
Covers Section II of Kastan's *From the Heart*

Welcome

Today's Topic: The focus of today's support group is from Section II of Kathy Kastan's book, *From the Heart.*

Discussion

Chapter 5: Body Image and the Sexual Self
Relaxation and Renewal

How can a heart event affect self-image? How can heart disease affect the way that you view yourself and how others view you? How can heart disease or risk change your sexuality?

Are there any "scars" from your heart event or heart-related diagnosis? Any new body sensations?

What can you do to lift yourself up and build your health? How do you talk to yourself? How can you change your thinking by talking to yourself differently?

How can you nurture a healthy mental attitude? What are positive ways to pamper yourself, your health and your heart?

Is health and beauty on the inside---or on the outside?

How do you manage stress? What were Kathy's suggestions?

Small Group Discussion: How can you better praise yourself or engage in positive self-talk? How can you count your blessings?

Chapter 6: Coping with Change
Your Family

How has your heart health or cardiac event affected your family? How has that made you feel? Has anything changed for the better or worse with your change in health? Who has it been the hardest on?

What have been the biggest changes after your cardiac diagnosis and how have you coped with them?

Do you know what you can and can't do? Do your friends and family know your strengths and limitations (if any)?

Have you set limits? Are you able to ask for help? Do you get the help that you need?

Are members of your family or circle of friends sensitive to your needs and are they good listeners? Are there any enduring points of conflict or difficulty among your close family circle or circle of friends subsequent to your event regarding your health and recovery?

Have you tried the "I" rather than the "you" messages?

How have you used your illness and recovery to strengthen relationships with others?

Are you back to "normal" again?

Have friends or family been over-protective or fearful? What are their worries? Have you "let go" of the superwoman thing? How have you done so? Or, how should you do so? Any tips to share?

How do you handle comments and people who are just not helpful---or who are hurtful?

How much time does it take to adjust after a cardiac event or change in heart health? Does everyone around you just adjust?

What is a caregiver? Do you have a caregiver? How are they coping? Have you developed a team approach?

Chapter 7: Strengthening Relationships
Friends and Society

Did your health affect or change your friendships?

Who is in your social network of friends and family?
Are you able to lean on them?

Did you feel isolated from family and friends due to your health?

What is a friendship inventory? What are you thoughts about taking a friendship inventory to focus your time and energy?

Who are your best friends and how do they support you?
How do you hold on to friends? How do you make time for friends? How do you make new friends?

Source: Lindquist, R., & Windenburg, D. (2010).

Appendix M. Women's Cardiac Support Group: Session IV

Women's Cardiac Support Group
"Book Club"
Session IV
Covers Section III of Kastan's *From the Heart*

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1. Welcome

2. Comments about Reading for today…

   Co-moderator volunteer?

   Kastan Part III:

   a. Managing Your Work Life: *Facing the Challenge*

      Discussion Questions:

      How was the transition back to work for you?
      How did you experience it---and why? What helped you through it?
      Did you change or modify your job?
      How do you experience and manage work-related stress?
      What is helpful in making work-related decisions?
      Have your priorities been re-set?
      What is "coming out' like?
      Did you re-invent your job or work roles?
      How did people around you handle your "news?"
      Did you assume a "second adulthood" identity?

   b. Negotiating the Health-care System

      Discussion Questions:

      What information is needed from the health care system to recover well?
      What are good and bad experiences? ---How do you learn from them?
      How do you find a doctor or provider that you trust? (And doesn't make you wait too long?)
      What is broken in the health care system?
      Do you know the Patient Bill of Rights? (p. 189) ---and Patient Responsibilities?
      How have you worked to improve your health?
      What problems might you have in advocating for yourself in the heal care system or with your doctor?

Do you consider before you go to your provider:
What is my main problem?
What do I need to do?---and Why?
How do you make the most of your doctor and other resources?
Do you have resources, help, or health care advocate?

c. Becoming an Advocate for Change: *The Bigger Picture*

Discussion Questions:

How can you make a difference in the fight against heart disease?
What do you do to help yourself and other women to be taken seriously in the health care system?
Are you an advocate for women with heart disease? Are you an advocate for yourself?
What can you do if your needs are not met?

3. Debrief Support Group "Book Club"

4. Adjourn

Source: Lindquist, R., & Windenburg, D. (2010).

Appendix N. University of Minnesota Approval Letter

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

D528 Mayo Memorial Building
420 Delaware Street S.E.
MMC 820
Minneapolis, MN 55455

Office: 612-626-5654
Fax: 612-626-6061
E-mail: irb@umn.edu or ihc@umn.edu
Website: http://research.umn.edu/subjects/

November 18, 2009

Arin G VanWormer
School of Nursing
Room 4-136 WDH
308 Harvard St S E
Minneapolis, MN 55455

RE: "Stress Management, Incentives, Logging, and Enhancements (SMILE) Study"
IRB Code Number: **0909M72652**

Dear Dr. VanWormer

The Institutional Review Board (IRB) received your response to its stipulations. Since this information satisfies the federal criteria for approval at 45CFR46.111 and the requirements set by the IRB, final approval for the project is noted in our files. Upon receipt of this letter, you may begin your research.

IRB approval of this study includes the consent form received November 05, 2009.

The IRB would like to stress that subjects who go through the consent process are considered enrolled participants and are counted toward the total number of subjects, even if they have no further participation in the study. Please keep this in mind when calculating the number of subjects you request. This study is currently approved for 12 subjects. If you desire an increase in the number of approved subjects, you will need to make a formal request to the IRB.

For your records and for grant certification purposes, the approval date for the referenced project is October 09, 2009 and the Assurance of Compliance number is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003). Research projects are subject to continuing review and renewal; approval will expire one year from that date. You will receive a report form two months before the expiration date. If you would like us to send certification of approval to a funding agency, please tell us the name and address of your contact person at the agency.

As Principal Investigator of this project, you are required by federal regulations to:
*Inform the IRB of any proposed changes in your research that will affect human subjects, changes should not be initiated until written IRB approval is received.
*Report to the IRB subject complaints and unanticipated problems involving risks to subjects or others as they occur.
*Respond to notices for continuing review prior to the study's expiration date.
*Cooperate with post-approval monitoring activities.

Information on the IRB process is available in the form of a guide for researchers entitled, What Every Researcher Needs to Know, found at
http://www.research.umn.edu/irb/WERNK/index.cfm

The IRB wishes you success with this research. If you have questions, please call the IRB office at 612-626-5654.

Sincerely,

Felicia Mroczkowski, CIP
Research Compliance Supervisor
FM/pm
CC: Ruth Lindquist

APPROVED
11/18/09
kens1001

Appendix O. Allina Hospital & Clinics Approval Letter

Research Subjects Protection Program
Institutional Review Boards
Internal Mail Route 10105
PO Box 43
Minneapolis, MN 55440-0043
612-262-4920
Fax 612-262-4953
www.allina.com

October 22, 2009

ALLINA
Hospitals & Clinics

Arin VanWormer, RN, MS
University of Minnesota - School of Nursing
Room 4-136 Weaver-Densford Hall
308 Harvard St. NE
Minneapolis, MN 55455

Re: **2702-1E**
Stress Management, Incentives, Logging, and Enhancements (SMILE) Study

Dear Ms. VanWormer,

Thank you for your letter dated October 19, 2009, revised application form, and revised consent form version 2 dated October 19, 2009 in response to the stipulations of the Abbott Northwestern Hospital Institutional Review Board (IRB) as described in Ms. Rumsey`s letter of October 5, 2009. The requested corrections and clarifications have been made; therefore, you are now fully approved and may start to screen and enroll participants into the above referenced study. You may use the lottery procedure rather than offering a gift card as suggested by the IRB reviewer. This final approval applies to Protocol received September 23, 2009 and consent form version 2 dated October 19, 2009. A copy of the consent form bearing the Institutional Review Board (IRB) approval stamp is enclosed for your records. Please use a copy of the consent form bearing the IRB approval when obtaining signatures for consent. The IRB file number has also been stamped on the upper right hand corner of the consent form.

Please inform the IRB immediately of any changes or modifications to the protocol, consent form or supporting documents prior to initiation. This includes protocol amendments, changes in the number of participants, etc. In addition, all subjects enrolled must fulfill all inclusion/exclusion criteria; any exceptions must have prior approval from the IRB. You must notify the IRB if any participants experience serious adverse events or events that occur at a frequency or intensity greater than that described in the approved consent form.

It is your responsibility to submit an annual Continuing Review Form to this office. Your study must be renewed on or before September 10, 2010. If your study has been completed or terminated prior to that date, please submit a final summary of your project in addition to the Continuing Review Form.

In any future correspondence with the IRB, please refer to the assigned study number, the principal investigator`s name and the name of the board that reviews this study.

On behalf of the IRB I wish you success with your research. If you have any questions or concerns, please call the IRB administrative office at (612) 262-4920.

Sincerely,

Ellen Stewart
IRB Manager